The Leiden developmental care project : effects of developmental care on behavior and quality of life of very preterm infants and parental and staff experiences

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CHAPTER 5

Parental stress and child behavior and temperament in the first year after the Newborn Individualized Developmental Care and Assessment Program (NIDCAP)

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Abstract

A randomized controlled trial compared basic developmental care (nests and incubator covers) and the Newborn Individualized Developmental Care and Assessment Program (NIDCAP) intervention (behavior observations and guidance by a trained developmental specialist) to evaluate the effect of NIDCAP on parental stress and infant behavior and temperament during the preterm infant's first year of life (n=128). The NIDCAP group tended to show more social relatedness behavior (p=0.011) at 1 year, especially when admitted > 1.5 months at the NICU where the intervention took place (n=44; p=0.006). Parents in the NIDCAP group reported positive experiences and effects on the well-being of their infant during admission. No effects were found on temperament, problem behavior or parental stress. Implications for NIDCAP implementation are discussed.

Introduction

The occurrence of a preterm birth affects both the infant and the family. Parents of preterm infants report more stress [1,2] and experience more maladaptation and need for support during the first year after delivery [3] than parents of infants born at term. Mothers of preterm infants showed symptoms of post-traumatic stress syndrome in a study by Holditch-Davis and colleagues [4]. Preterm infants showed more externalizing and internalizing behavior problems in a meta-analysis in 13 out of 16 studies (81%) and more attention deficit hyperactivity disorder symptom behavior in 10 out of 15 studies (67%) [5]. The (posttraumatic) stress of parents of very preterm infants furthermore correlated with more problem behavior of their children at 36 months [6] and increased sleeping and eating problems as reported by parents [7].

Focus in neonatal caregiving has shifted to a more individualized approach with more emphasis on the family and in this context the Newborn Individualized Developmental Care and Assessment Program (NIDCAP) [8] was introduced in the 1980's. This program is based on the synactive theory of development [9] where the infant's individual behavior is observed along four channels of communication: autonomic system (skin colour, respiration etc.), motor system (posture, tone and movements), state organization system (type and range of states available to the infant from sleep to aroused and state transition) and attention and interaction system (the infant's ability to come to an alert, attentive state and to utilize this state to handle stimuli from the environment), by a NIDCAP trained developmental specialist. The infant's efforts at self-regulation and interaction are observed through approach and avoidance behaviors [9,10]. A narrative of the observation is written and individual recommendations to modify the infant's environment and caregiving, based on the observation, are discussed with parents and other caregivers and parents are supported in becoming more actively involved in the caregiving process [8,11]. An example of a recommendation based on the infant's behavior is the timing of pauses during caregiving, based on the infant's individual behavioral cues. An example of involving parents in caregiving is giving them recommendations how to comfort their child during the caregiving by the nurse.

The results of NIDCAP intervention studies in the United States and Sweden show positive outcomes [12-19]. A randomized controlled trial in three centers in the United States found less parental stress at 2 weeks after the expected date of confinement in a NIDCAP intervention group [13]. A Swedish study found a positive impact of NIDCAP on behavior at preschool age [19]. A recent review on the effects of various forms of Developmental Care [20] concluded that although limited benefits and no major harmful effects were found, the significant effects were mainly based on studies with small sample sizes and that several of these findings were not supported in other settings.

This study explores the effect of the individualized and family centered NIDCAP program on infant temperament at 9 months and infant behavior and parental stress at 1 year of the infant's corrected age, in comparison with a basic form of developmental care. We expected that the NIDCAP intervention would have more effect when the duration of the intervention was longer. In this context, the effect of the NIDCAP was also studied within a subgroup of infants who were admitted for more than 1.5 months at the NICU where the study took place.

Methods

NIDCAP intervention

A randomized controlled trial was conducted to explore the effect of individual care plans and guidance through the use of the NIDCAP (Newborn Individualized Developmental Care and Assessment Program) behavioral and observation tool [8,11], compared to a basic form of developmental care (nests and incubator covers). The intervention consisted of NIDCAP observations of the infant before, during and after the caregiving [8] every 7 to 10 days by a NIDCAP trained developmental specialist. The trained developmental specialist wrote reports and discussed individual recommendations with parents and other caregivers and supported them in giving care to the infant. The first observation was done within 48 hours after birth. A nursing team that had received additional clinical lessons in the NIDCAP approach was assigned to the infants in the NIDCAP intervention group. The control group

received the basic elements of DC and was given nests to support flexed positioning and incubator covers to shield the infants from light and sound stimuli. These basic elements of developmental care are often seen as a first step for hospitals before they decide to train personnel, which costs more time and money. This study wanted to explore the additional value of the individualized approach of the NIDCAP observations and guidance.

Subjects

Infants born from July 2002 to August 2004 with a gestational age below 32 weeks in a NICU at two locations in the Netherlands were randomly assigned (sealed envelops with cards) to a control or NIDCAP group within 48 hours after birth. Exclusion criteria were: infants of drug-addicted mothers and infants with congenital heart disease or other major birth anomalies. According to protocol, infants in both the NIDCAP and basic DC control group who were admitted for less then 5 days were excluded from follow-up analysis because the duration of the NIDCAP intervention was hypothesized not to be long enough to measure any effect. A sample size power calculation showed that 140 infants (70 control and 70 intervention) were needed to show a significant difference with a power of 80%, based on the expected difference of half a standard deviation on the primary outcome (Bayley Scales of Infant Development, standard deviation of 15). In total 168 infants were included after parental informed consent was obtained. The Medical Ethics Committees of both locations approved this study.

Measures

All ages mentioned hereafter are corrected for prematurity. At 9 months of age the Infant Behavior Questionnaire Revised (IBQ-R) [21] was sent to the home address of parents to measure infant temperament. At the infant's age of 1 year, parents were given a modified version of the Infant-Toddler Social and Emotional Assessment (ITSEA) [22] to measure infant behavior and the Nijmegen Parenting Stress Index short version (NOSIK) [23], which measures parenting stress, at the follow-up clinic. Parents were asked to give their general opinion regarding the positive or negative effects that the control or intervention care had on their infant in an open question on the final page of the questionnaires given at 1 year.

Parent and child characteristics:
Demographic variables included parental age, educational level and country of birth (the Netherlands/other). Infant characteristics at birth included gender, gestational age, birth weight and the Clinical Risk Index for Babies (CRIB) score. The CRIB score [24] assesses initial neonatal risk by scoring birth weight, gestational age, congenital malformation, maximal base excess in the first 12 hours and minimum and maximal oxygen requirements in the first 12 hours after birth.

Infant temperament (IBQ-R) at 9 months:
At 9 months of their infant's age, parents completed the Infant Behavior Questionnaire Revised (IBQ-R) [21]. This questionnaire contains 191 behavior items which can be rated on a 7 point Likert scale (1=not present, 7=always present) with an extra "does not apply" answer possibility which received no numerical score when calculating mean scores for the scales. The items measured 14 behavior scales being: distress to limitations, fear, sadness, rate recovery from distress, activity level, smiling and laughter, high intensity pleasure, perceptual sensitivity, approach/positive anticipation, vocal reactivity, duration of orienting, low intensity pleasure, soothability and cuddliness. Cronbach's alpha for scale reliability (with infants 9-12 months) ranged from 0.71-0.87 [21] in a previous study. In the current study alpha's ranged from 0.74-0.89. The IBQ was translated forward/backwards into Dutch (translated from English into Dutch and then checked by having a native English speaker translate it back into English). The questionnaire and permission to use it were obtained from the author.

Infant behavior (modified ITSEA) at 1 year:
At 1 year of the infant's age parents completed a Dutch translation of the Infant-Toddler Social and Emotional Assessment (ITSEA) [22]. This questionnaire was translated into Dutch and some items were deleted from the original questionnaire because of the young age of the infants. The following subscales were excluded from the original ITSEA: peer aggression, general anxiety (i.e. "worries about own body"), prosocial peer relations and the maladaptive scale. The modified questionnaire consisted of 15 behavior subscales, divided over 5 main factor domains: externalizing

(activity/impulsivity and aggression/defiance), internalizing (depression/withdrawal, separation distress and inhibition to novelty), dysregulation (sleep problems, negative emotionality, eating problems, sensory sensitivity), competence (compliance, attention, imitation/play, mastery motivation, empathy) and social relatedness.

Other than the above described deleted subscales, zero to three items were removed from the remaining subscales in each domain. The modified questionnaire used in this study consisted of 107 items with answers on a 3 point Likert scale (0=not true/rarely, 1=somewhat true/sometimes, 2=very true/often). In a previous study the original questionnaire was validated [22]. In the current study alpha's ranged from 0.80 to 0.86 (alpha of 0.80 for social relatedness) for domains of the Dutch translated questionnaire. This is comparable to the Cronbach alpha's, ranging from 0.88 to 0.94 (and an alpha of 0.56 for social relatedness), found for the domains of the original ITSEA [22], which suggests that the exclusion of items did not affect the reliability of the domains. The mean domain scores ranged from 0 to 2 and a higher score represented more problem or competence behavior.

Parenting Stress (NOSIK) at 1 year:
The Nijmegen Parenting Stress Index (NOSI) [23] is a Dutch version of the Parenting Stress Index (PSI) [25]. At 1 year parents were asked to complete the short version, the NOSIK. The NOSIK consists of 25 parental stress related statements (the items that performed best in the NOSI complete version) with answers on a 5 point Likert scale ranging from 1 (totally disagree) to 5 (totally agree). The NOSIK has a total parenting stress scale and a parent and a child domain. The Cronbach's alpha score of the total scale of the short version, NOSIK, was good (α=0.95) [23] and this was confirmed in the present study (α=0.94).

Analysis
For statistical analysis SPSS 11.0 for Windows was used. Average scale scores were calculated using the non-missing items, if the scale contained no more than 30% missing items. The infant and parent characteristics were

compared with the Chi-square test, the Chi-square test for trend, the two-sample t-test or the non-parametric Mann-Whitney test, where appropriate.

Mean scale scores of the two groups were compared using a covariate analysis in which the infant and parent characteristics and the completion day after the age of 1 year were included as covariates. This was done for a more precise estimation of the difference between the two groups and to correct for possible confounders. The effect of the NIDCAP intervention was also explored (covariance analysis) within a subgroup of infants who were admitted for > 45 days at the NICU where the study took place.

The percentages of parents scoring high (>90th percentile) on parental stress were reported and compared between both groups using a NOSIK reference group consisting of non-clinical Dutch mothers, derived from the manual [23]. Because of multiple testing a significance level of below 0.01 was chosen.

Results

Subjects

During the RCT 168 infants were included. At 9 months 146 parents received the IBQ questionnaire of which 134 (92%) were returned (Figure 1). The return rate of all 168 included children (minus 14 infant deaths) was 87%. At 1 year 144 parents received the questionnaire of which 128 (89%) were returned (Figure 1). The return rate of all 168 included children (minus 14 infant deaths) was 83%. The loss to follow-up as displayed in Figure 1 also included infants transferred within 5 days of admission.

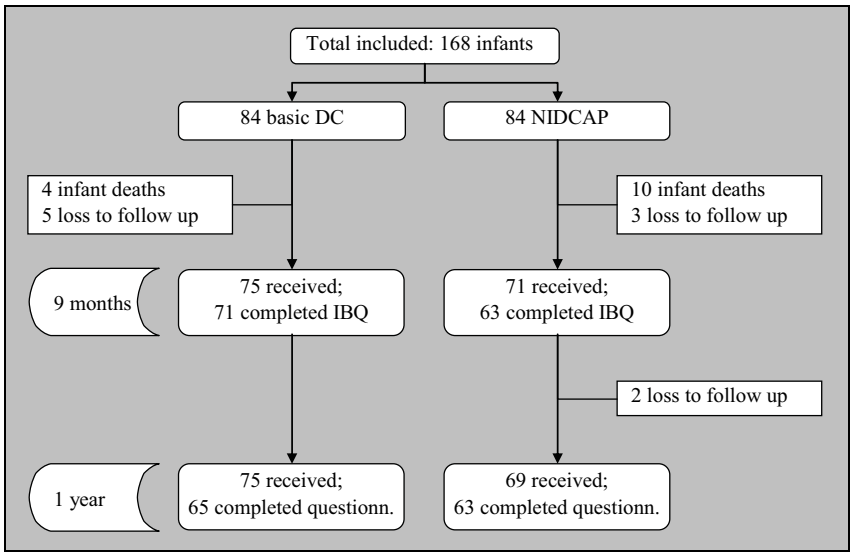

Figure 1. Loss to follow up and returned questionnaires.

The infant and parent characteristics of the parents who returned the questionnaire at 1 year were similar in both groups (Table 1), with the exception of maternal age (p=0.007), which was added as one of the covariates in the final covariance analysis. Mothers in NIDCAP intervention group were on average 2 years younger compared to mothers in the basic DC group and mothers in both groups were on average in their early thirties when completing the questionnaire.

		NIDCAP n(%) or mean(sd)	Basic DC n(%) or mean(sd)	Difference p-value ^
RCT (intervention: NIDCAP - control: basic DC)		**N= 63**	**N= 65**	
Completed by …	mother	50 (79%)	57 (89%)	.32
	father	9 (14%)	5 (8%)	
	both	4 (6%)	2 (3%)	
Gender (male)		38 (60%)	33 (51%)	.28
Gestational age at birth (weeks)		29.6 (1.5)	29.2 (1.6)	.17
Birth Weight (grams)		1269 (318)	1244 (349)	.67
CRIB score 24		2.8 (2.8)	3.0 (3.1)	.70
Maternal age at infant's birth (yrs)		29.9 (5.1)	32.3 (4.9)	.007*
Maternal education level #	low	17 (27%)	12 (19%)	.31
	intermediate	24 (38%)	26 (41%)	
	high	22 (35%)	26 (41%)	
Country of birth mother (the Netherlands)		51 (81%)	58 (91%)	.12
Paternal age at infant's birth (yrs)		32.1 (5.8)	33.9 (5.5)	.08
Paternal education level #	low	12 (20%)	9 (15%)	.65
	intermediate	20 (34%)	32 (52%)	
	high	27 (46%)	21 (34%)	
Country of birth father (the Netherlands)		48 (77%)	50 (78%)	.92
Duration of admission in NICU where study took place (days)▫		38 (6;160)	36 (5;286)	.60
Completion after infant's age 9 months (days)▫		6 (-35;163)	7 (-12;140)	.66
Completion after infant's age 1 yrs (days)▫		9.5 (-35;119)	15 (-42;101)	.40

Table 1. Comparison of infant and parent characteristics of completed questionnaires at 1 year.

* $p < .01$

^ T-test / Chi-square test (for trend)

~ Low = vocational education, intermediate = high school, high = college education/ university

▫ Non parametric Mann-Whitney test (median and range per group)

Within the group of included infants whose parents did not receive or complete the questionnaire at 1 year (because of death or loss to follow up and nonresponders), both groups (basic DC N=19, NIDCAP n=21) were comparable concerning their gender, gestational age at birth and birth weight (data not shown).

Infant temperament at 9 months

No significant differences were found on the subscales of the IBQ measuring infant temperament.

IBQ 9 months; 1(never) -7(often) ~	NIDCAP mean (sd)	Basic DC mean (sd)	NIDCAP-DC Difference (99% CI) #
Distress to limitations	3.45 (.93)	3.45 (1.05)	.02 (-.48;.53)
Fear	2.59 (.68)	2.47 (.87)	.06 (-.33;.44)
Sadness	3.29 (.99)	3.35 (1.02)	-.11 (-.64;.42)
Rate recovery from distress	5.44 (.87)	5.44 (.92)	.02 (-.43;.48)
Activity level	3.88 (.92)	4.15 (.85)	-.33 (-.78;.12)
Smiling and laughter	5.15 (.91)	5.25 (.74)	-.03 (-.45;.40)
High pleasure	5.99 (.64)	6.04 (.61)	.05 (-.27;.36)
Perceptual sensitivity	4.00 (1.28)	4.33 (1.37)	- .40 (-1.18;.38)
Approach	5.15 (.69)	5.09 (.69)	.19 (-.17;.55)
Vocal reactivity	4.71 (.82)	4.75 (.86)	-.02 (-.48;.43)
Duration of orienting	3.74 (.98)	3.47 (1.06)	.26 (-.29;.81)
Low pleasure	5.24 (.88)	5.48 (.80)	-.08 (-.54;.39)
Soothability	5.53 (.84)	5.51 (.74)	.03 (-.40;.46)
Cuddliness	5.42 (.87)	5.48 (.78)	-.07 (-.50;.37)

Table 2: Infant temperament at 6 months (IBQ)

~ Higher scores represent the child displaying more of the behavior as described

Covariance analysis; difference (99% CI), corrected for the completion day after the age of 9 months, infant gender, gestational age, birth weight, CRIB and the age, educational level and country of birth of parents. Minimal N covariance: NIDCAP=49, basic DC=45.

Infant behavior at 1 year

No significant differences were found on infant behavior at 1 year between both groups. Social relatedness behavior tended to be higher in the NIDCAP group, compared to the infants that received basic DC (p=0.011).

ITSEA 1 yr (range 0-2) Mean score on domain	NIDCAP mean (sd)	Basic DC mean (sd)	NIDCAP-DC Difference #
Problem behavior ~			**Diff (99% CI) #**
Externalizing	.53 (.32)	.43 (.28)	.07 (-.09;.22)
Internalizing	.52 (.25)	.47 (.23)	.07 (-.05;.20)
Dysregulation	.45 (.28)	.42 (.22)	.02 (-.11;.14)
Competences ~			
Competence	1.06 (.30)	1.04 (.31)	.03 (-.12;.18)
Social Relatedness	1.71 (.20)	1.63 (.25)	.11 (-.001;.23)*

Table 3. Comparison NIDCAP and basic DC on infant behavior (ITSEA) at 1 year of corrected age.

* $p < .05$

\# Covariance analysis; difference(99% CI), corrected for the completion day after the age of 1 year, infant gender, gestational age, birth weight, CRIB and the age, educational level and country of birth of parents. N covariance: NIDCAP=58, basic DC=61.

~ For all ITSEA total domains: higher mean score represents more problem / competence behavior

Parenting stress at 1 year

No significant differences were found on parental stress between the basic DC and NIDCAP group. Although not significant, the total stress scores in the NIDCAP intervention group were higher compared to the basic DC control group. The percentage of parents with a non-optimal parental stress score (> cut-off point 90th percentile, reference group of Dutch mothers) was approximately 10% for both groups and comparable to the percentage of parents scoring non optimal in the Dutch reference group.

	NIDCAP Mean (sd)	Basic DC Mean (sd)	NIDCAP-DC Difference #	NIDCAP % ≥ 90 perc.	Basic DC % ≥ 90 perc.	NIDCAP-DC Chi² ^
NOSIK 1 year (range 1-6) ~			**(99% CI diff.) #**	**% (n)**	**% (n)**	**p-value**
Total score Parent Domain	1.76 (.77)	1.75 (.76)	.04 (-.38;.45)			
Total score Child Domain	2.04 (1.00)	1.95 (.83)	.14 (-.37;.65)			
Total Stress score	1.92 (.86)	1.86 (.76)	.10 (-.35;.54)	10 % (6)	9 % (6)	.96

Table 4. Comparison NIDCAP and basic DC on parental stress at 1 year (NOSIK, short version).

\# Covariance analysis; difference (99% CI), corrected for the completion day after the age of 1 year, infant gender, gestational age, birth weight, CRIB and the age, educational level and country of birth of parents. N covariance: NIDCAP=58, basic DC=61

^ Chi-square test % scoring non optimal (p-value)

~ For all NOSIK scales: higher mean score represents more parental stress

Subgroup longer duration of intervention
Social relatedness was significantly better in the NIDCAP intervention group (Difference DC-C=0.27, 99%CI=0.02;.51, p=0.006) within a subgroup of 44 infants admitted > 45 days to the NICU in which the study took place (NIDCAP=21, DC=23).

Parental remarks on the care given to their child
Almost all parents expressed that they felt that the caregiving their child had received during admission had a positive effect. Thirty-one parents in the basic DC group (49% of the 63 parents that completed the questionnaire) and 42 parents in the NIDCAP group (65% of the 65 parents that completed the questionnaire) commented on the positive effect of the care their child received.
Some parents in the control group indicated that it was difficult for them to judge if this control care (basic DC) had any effects on their child but were overall positive with regards to the care their child had received and its effect on their infant. One parent specifically reported that the infant seemed to suffer less from unusual stimuli and that it seemed easy to apply and use the basic elements of developmental care in the unit.

Parents in the NIDCAP intervention group often attributed their child's positive behavior and development to the NIDCAP care. One parent for example stated that "He became a lot calmer and almost never cried. The reaction to NIDCAP was very noticeable". Parents furthermore indicated that the NIDCAP helped them during the admission of the infant and taught them how to observe their baby's behavioral cues. Parents commented: "It makes it easier for parents to gain and maintain contact with their infant" or "I got to know my baby really early" or "She is calm and feels safe, we now know when she is bothered by too many stimuli so we can remove them". Another parent stated that it made the period at the NICU easier for them. Parents indicated that they mainly observed the positive effects of NIDCAP during the period of admission. They, for example, reported: "During caregiving he seemed to appreciate the special care given to him but I find it difficult to comment on this" and "I mainly noticed the effect during admission, during

the one-on-one contact with the nurse, but I do not think the effects last until now (1 year of age)".

Discussion

Parents expressed positive experiences with NIDCAP and reported positive effects on the comfort and well-being of their infant during admission. However, no significant effects were found of the NIDCAP intervention, compared to basic developmental care, on infant temperament at 9 months and infant behavior and parental stress at 1 year of the infant's corrected age. There was a tendency of improved social relatedness behavior as measured by the ITSEA at 1 year in the NIDCAP intervention group and this difference was significant in infants who received the intervention for more than 1.5 months.
The social relatedness domain of the ITSEA consists of three constructs, being social approach (i.e. "Is affectionate with loved ones"), relatedness (i.e. "Looks for you when upset") and social attention (i.e. "Looks right at you when you say his/her name"). A previous RCT [26] in the same Dutch NICU compared basic DC (standardized incubator covers and nests) with standard care (no forms of nests or covers). This RCT found a positive effect of basic DC on mastery motivation competence behavior at 1 year of age and no difference on social relatedness with 139 questionnaires (from the parents of 192 infants included at birth). One of the characteristics of the NIDCAP is that it focuses on the infants' behavioral cues for interaction with their caregivers and parents, which might have intensified the infants' social relatedness with their parents or changed the way parents perceived their child.

No effects were found of NIDCAP, compared to basic DC, on infant temperament at 9 months of age. A study by Keretes showed that the IBQ temperament scores of preterm infants at 6 and 12 months of age resembled the scores of term infants [27]. Furthermore, mean IBQ scores found in the current study resembled the scores of a sample of 9-12 months old infants (N=120) from a normal population in the USA [21].

The NIDCAP intervention did not improve parenting stress in the total study group and in the subgroup with a longer admission duration, as measured by a short version of the Dutch version (NOSIK) of the Parenting Stress Index (PSI) questionnaire. Although it was presumed that parenting stress of parents of a premature born infant is higher than of parents with a term infant, parental stress scores of the parents in both study groups resembled the scores of a reference group of mothers from the normal Dutch population.

The significant decrease of parental stress in the NIDCAP group in the three-center study by Als [13], as measured with the PSI questionnaire, was not found in the current Dutch study. One of the reasons could be that the average duration of the intervention in our study was relatively short, compared to the three-center study by Als [13], because infants admitted to the academic location of the NICU were transferred to a medium care unit of a local hospital when they became more stable. The three-center study by Als reported an average admission duration of 100 days until discharge while the current study showed a median admission duration of 36 (basic DC group) and 38 (NIDCAP group) days. Analysis of the infants admitted for more than 45 days showed a significant improvement of social relatedness at 1 year ($p=.006$) in the NIDCAP group. Stress scores were also a bit lower, although not significantly (data not shown) in the subgroup, instead of higher as in the total study group, which resembles the hypothesis of decreased stress. This suggests that a longer intervention duration might have a more positive effect on infant social relatedness behavior and parental stress.

Parents' remarks on the effect of the NIDCAP intervention at the end of the questionnaire indicated overall positive effects of NIDCAP on parents' experiences and the comfort and well-being of their infant during admission. However, no significant differences were found between the NIDCAP group and the basic DC group on the outcomes of the questionnaires. This suggests that future research should focus on the infant's comfort and pain-related infant behavior during admission or shortly after the intervention has ended, such as pain assessments [28] or measurements of infant behavior (for example: the Assessment of Preterm Infants' Behavior [29]).

This Dutch study furthermore showed that the effect of the NIDCAP intervention might be influenced by the Dutch setting and circumstances (i.e. the transfer policy), which suggests that it is difficult to generalize results from NIDCAP intervention studies. During the implementation of developmental care or NIDCAP in the Netherlands, it is important to ensure a continuation of developmental care by involving regional hospitals more and by evaluating the transition to another hospital and the transition after the infants are discharged to go home.

The NIDCAP training costs approximately 4.000 US$ per person and the training guide states that during training one needs to perform 20 observations and to observe 1 infant at the NICU biweekly or weekly from admission to discharge and one observation at the infant's home after discharge, which can be time-consuming [30].

Further research is needed to evaluate if positive outcomes can outweigh the cost and labor intensive characteristics of the NIDCAP intervention and a more complete costs-benefits analysis is warranted. Other medical and (neuro)developmental outcomes of the current study are needed for a complete representation of the effects of this study. Furthermore, this study shows that future study of an intervention with a longer duration and with other outcomes might be valuable. Until now, this study has showed a small positive effect on a domain of infant behavior at 1 year and found no other group differences. The positive effects reported by parents are also valuable and further evaluation of parents' experiences with NIDCAP and the experiences of the personnel at the NICU with NIDCAP might shed some light on outcomes that need to be explored in future randomized controlled trials.

This study suggests that it is valuable to implement a least several basic elements of developmental care in the Dutch setting, until other outcomes of future research are known. These basic aspects of developmental care might encompass the use of standardized nests and incubator covers, lower levels of sound, light and activity in the unit and clinical lessons for NICU personnel

on infant behavior, based on the NIDCAP observational tool and the synactive theory of infant development.

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