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 7

General discussion

Discussion

Developmental care interventions that focus on the individuality of the infant, family and environment, such as the Newborn Individualized Developmental Care and Assessment Program (NIDCAP) are recently being integrated in Dutch Neonatal Intensive Care Units (NICU) in various forms. This thesis reported on the effects of a basic form of Developmental Care and the effects of the NIDCAP intervention, with individual observations and guidance, on the behavior and health related quality of life (HRQoL) of very preterm infants born < 32 weeks of gestation and their parent's experiences and stress. This thesis furthermore explored the nursing and (para)medical staff's experiences with the implementation of NIDCAP in their unit.

The study consisted of two consecutive Randomized Controlled Trials (RCT). The first trial measured the effect of basic developmental care (basic DC: using standardized nests to support positioning and incubator covers to protect the infant from sound, light and activity coming from the nursery), compared to standard care. The second trial explored the effect of the NIDCAP intervention (individualized observations and guidance by a developmental specialist), compared to basic DC. We expected the basic form of developmental care to positively influence health and behavior because of the stimulation of rest through the protection from environmental stimuli and the support of positioning. We also thought that basic DC would decrease parental stress because parents might perceive their infant as being more comfortable in the nests and underneath the incubator covers. We expected the individual characteristics of the NIDCAP observations and guidance in the second trial to further intensify these positive effects, especially on parental stress. The somatic and developmental outcomes of the infant (the medical outcomes during admission and the neurological and developmental examinations at 1 and 2 years of age) will be reported and discussed in another thesis.

Effect of developmental care on parent's experiences and stress

The first trial revealed that basic DC did not decrease parental stress during admission or at 1 or 2 years of the infant's age and did not increase parental

confidence or perceived nurse support during admission. The more individualized and family-based characteristics of the NIDCAP observations and the guidance by a NIDCAP trained developmental specialist during the second RCT had no effects on parental stress, confidence and perceived nurse support during the infant's admission and parental stress at 1 and 2 years of the infant's age.

As in other studies that measure parental stress of parents of preterm born infants, we found higher stress levels of mothers compared to fathers during the infant's admission. In the second trial, we found a decrease in the difference between the stress levels of mothers and fathers in the NIDCAP group, compared to the basic DC group. The effects of higher paternal stress levels on infants and the family have, to our knowledge, not been studied before. A study by Miles et al. concluded that the higher stress levels of mothers, especially on the parent role alteration stressors (as also found in the current study), suggests that mothers are more affected by the loss of the caretaking role than fathers [1]. Jackson and colleagues [2] interviewed parents and concluded that it was often difficult for fathers to get leave from work and that they had no choice but to leave the care to the nursing and medical staff. The aim of the NIDCAP to equally involve both parents in the caregiving and to approach them as the main caregivers could have led to higher stress levels in fathers, which became more similar to maternal stress levels.

Effect of developmental care on health-related quality of life

No significant effects were found of basic DC in the first RCT and the NIDCAP observations and guidance in the second RCT on the infant's health-related quality of life at 1 year. To our knowledge HRQoL has not been previously used as an outcome to measure the effect of a developmental care intervention. Our hypothesis was that the nests and incubator covers would increase the infant's opportunities for rest and, as a result, would improve the infant's health and health-related quality of life. Most children had optimal HRQoL scores (score of 100), which did not leave much of a window of opportunity to increase HRQoL.

Effect of developmental care on infant behavior

In the first RCT, a positive effect was found of basic DC on the competence behavior scale and its subscale mastery motivation of the ITSEA infant behavior questionnaire [3], completed at 1 year of corrected age. This indicates that the infants that received basic Developmental Care (standardized incubator covers and nests) showed more curiosity, persistence and enjoyment with small accomplishments and that they were more often well-behaved and obedient at 1 year of corrected age, compared to the infants that received standard care. The effect on infant competence behavior might be caused by the protective characteristics of the nests and covers that allowed the infants to rest and gain more control over their behavior. No effects were found on problem behavior at 1 and 2 year. At 2 years of age the CBCL [4] was given to measure problem behavior. This questionnaire does not measure competence behavior and therefore it was not possible to measure if the positive effect on competence behavior found at 1 year had persisted at 2 years of age.

In the second RCT, social relatedness behavior was better in the NIDCAP intervention group (compared to the basic DC control group) at 1 year of the infant's age, especially when the intervention duration was longer than 1.5 months. The social relatedness scale encompasses social approach ("Is affectionate with loved ones"), relatedness ("Looks for you when upset") and social attention ("Looks at you when you say his/her name"). 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. No effects were found on infant temperament at 9 months and infant problem behavior at 1 year of age during the second RCT. The difference found in the first RCT on infant competence behavior at 1 year of age, was not found in the second RCT. In both trials we found no effects on problem behavior and we only found an effect of both interventions on one behavior domain of the ITSEA, which encompasses only a part the behavioral spectrum of the infants.

Comparison to other NIDCAP studies

Previous studies show positive outcomes of the NIDCAP intervention [5-13]. A recent study using a three-center randomized controlled trial [6] found promising effects of the NIDCAP intervention on different outcomes, such as shorter duration of parental feeding, transition to full oral feeding, intensive care and hospitalization; lower incidence of necrotizing enterocolitis; reduced discharge ages and hospital charges; improved weight, length and head circumferences. This study found several effects on behavior at two weeks after the expected due date, such as enhanced autonomic, motor, state, attention and self-regulatory functioning on the Assessment of Preterm Infants' Behavior (APIB) [14] and reduced need for facilitation during the APIB. The three-center study also found lowered family stress on the Parenting Stress Index and enhanced appreciation of the infant. A recent study by Als and colleagues [7] with infants 28-33 weeks gestation and free of known developmental risks found enhanced brain function and structure (on neurobehavior assessment, developmental test, EEG and MRI) in the NIDCAP intervention group (n=16). This study in the USA found no effects on medical outcome variables at 2 weeks and 9 months of corrected age [7].

In contrast to what we expected, our study found no significant, clinically relevant differences between the basic developmental care and NIDCAP group and controls on parental stress and the infants' problem behavior and health-related quality of life. We were therefore not able to replicate the positive findings on parental stress and behavior found in the three center NIDCAP study [6]. In comparison to the current study, the mean gestational age at birth in the sample of the three center NIDCAP study was lower and the hospital stay and stay at the NICU where the intervention took place was noticeably longer.

Two NIDCAP studies took place in Sweden [15] and it is possible that the situation of a European country is more comparable to the Dutch situation. The first study consisted of two consecutive study periods of control (n=21) and intervention (n=21) care. This study found no significant differences in requirement for ventilatory support or weight gain for preterm infants with a birth weight below 1500 grams [15]. At 3 years of corrected age, improved

hearing-speech development, improved child behavior and improved child communication regarding mother-child interaction was found in the NIDCAP group [10]. A second study, with a randomized controlled design, was performed a year later with 25 infants born below 32 weeks of gestation and in need of ventilatory support. This Swedish RCT found less days of continuous positive airway pressure (CPAP) and oxygen was withdrawn at a younger post conceptual age in the NIDCAP intervention group [12]. This second Swedish study also found improved mental development at 1 year of corrected age [16] and a positive impact on infant behavior at 5,5 years of corrected age [13]. However, the sample size of the Swedish RCT was small because inclusion was terminated before the required number of infants was included because of spill over effects and other methodological reasons. The Swedish study recently reported on mothers' perception of NIDCAP [17] and concluded that although mothers in the NIDCAP group perceived more nurse support and closeness to their infant, they also expressed more anxiety. The authors suggested that higher anxiety might be a sign of early bonding [17].This finding is comparable to our finding of increased parental stress after basic DC and increased paternal stress after NIDCAP.

Meta-analysis of the NIDCAP data shows only small benefits of the NIDCAP intervention on oxygen requirements during admission [18,19]. A recent Cochrane review [18] discussed that a large number of outcomes showed no or conflicting effects and that the main effects were mostly found using small RCT's and could not be replicated in other small trials. Another review [19] emphasized that the methodological quality of NIDCAP studies is poor and a cost-benefits analysis seems appropriate because of the expensive and labor intensive characteristics of the NIDCAP intervention. Sizun and Westrup [20] have called for more research and argue that a large randomized controlled trial with multiple centers, long term neurobehavioral and developmental outcomes and a cost-effectiveness analysis seems of importance.

In the context of these reviews, the current study provides important additional information regarding the outcomes of two large consecutive RCT's measuring the effect of a basic form of developmental care and the additional effect of the individualized aspects and guidance of the NIDCAP

intervention in the Netherlands until 2 year of the infant's corrected age. This RCT found only small differences on competence behavior and social relatedness behavior and was not able to replicate the findings of reduced parental stress levels on the Parenting Stress Index questionnaire found in the three-center study in the USA. Also, no effects were found on the health-related quality of life of the infants. The NIDCAP reviews and meta-analysis call for studies in different settings and the current study shows that the NIDCAP has limited benefits in the Dutch setting with regards to the outcomes described in this thesis. Other infant outcomes of the current study need to be reviewed before a complete representation of effects can be given.

Evaluation of parents and staff experiences

Next to the results based on standardized questionnaires, the experiences of parents and the nursing and medical staff with NIDCAP are also of importance when evaluating the effect of NIDCAP. In this context, parents were asked to complete an open-ended question on the final page of the questionnaire at 1 year where they were able to indicate if the care their child had received had positive or negative effects. Parents overall indicated positive effects on the well-being of their infant during admission and on their own experiences during the admission of their infant.

An evaluation of the experiences of the nursing and (para)medical staff after the implementation of NIDCAP showed that the staff reported positive attitudes and experiences towards NIDCAP. Staff members felt that using NIDCAP is fulfilling and leads to improvements in the infant's development, health and well-being. The main problem with the NIDCAP observations seemed to be its time-consuming characteristics. In addition, some standard developmental care recommendations might worsen job conditions (for example because of reduced light levels at the unit). The nursing staff was more positive compared to the medical staff. The use of the NIDCAP method during caregiving was related to a higher intention, perceived behavioral control (their perceived control over using NIDCAP during caregiving) and subjective norm (the norm about using NIDCAP in the unit and the perceived importance of these norms). Although respondents indicated sufficient

abilities and knowledge they also indicated a need for ongoing information and guidance.

The evaluation of staff opinions led to the following recommendations regarding the implementation of NIDCAP: easy access to continuous and up to date information about NIDCAP and NIDCAP related issues and research, continuous clinical lessons and practical guidance, a multi-disciplinary approach and a multi-disciplinary NIDCAP team, possibilities to improve and discuss NIDCAP related job conditions (such as the reduction in light) and possibilities to review improving (time)efficiency. The applicability of these recommendations is dependent on the characteristics and available resources in the unit.

In conclusion, parents and the nursing and medical staff reported positive experiences with NIDCAP, especially with regards to the infant's comfort and wellbeing during caregiving, but this does not result in significant differences on the questionnaires given during admission and at 1 and 2 years of the infant's corrected age.

Research implications: Duration of intervention

The infants in this study were admitted for on average approximately 1 month to the NICU where the study took place. The NICU's in Dutch academic hospitals, such as the unit in Leiden, are mainly specialized in intensive care and infants are transferred to a regional hospital as soon as they become more stable. Therefore the duration of admission was sometimes short. We found that the positive effect of the NIDCAP intervention on social relatedness at 1 year was more profound if the duration of intervention was longer. This raises the question if the duration of the intervention in this study was long enough to measure significant effects. The three-center NIDCAP trial in the USA [6] found positive effects on parental stress and infant behavior with infants who were admitted for a more extended period of time (mean admission duration until discharge of approximately 100 days). These positive outcomes were not found in the current study. Interventions during admission with home visits after discharge have also found promising effects on parental stress [21] and infant problem solving and behavior ratings [22].

Following the results of the current study, compared with the results of other studies, it is recommendable to study a NIDCAP based intervention with a longer duration. In the context of the Dutch transfer policy of the NICU's in the academic hospitals, it is important to make sure that the special care is being continued in the regional hospitals. Regional developmental care or NIDCAP teams might enhance the communication between the academic and regional hospitals. In addition, a study exploring the effects of a developmental care based intervention including home visits after discharge seems recommendable. It is not difficult to imagine that parents might appreciate some guidance and recommendations after discharge, when they are left on their own to take care of their infant in the different circumstances at home. The need for home visits from the parent's point of view could be evaluated with a short qualitative parent questionnaire or interview.

Research implications: Outcome measures

This thesis explored parent outcomes during admission and parental stress and infant behavior and health-related quality of life at 1 and 2 years of the infant's corrected age with standardized questionnaires. Both parents and the nursing and (para)medical staff observed a positive effect of NIDCAP on the well-being and comfort of the infant during admission. This effect observed by staff and parents is not confirmed by the results on the outcomes measured with the standardized questionnaires. The well-being and behavior of the infants during admission was not measured in the current study. The observed effect on the infant's well-being by parents and staff suggest that it might be worthwhile to measure infant comfort through infant pain assessment [23] or by using the NIDCAP behavior observation sheets [24]. Infant behavior might also be actively tested during admission by administering, for example, the Assessment of Preterm Infants' Behavior (APIB) [14], which is used as an outcome measure in the three center NIDCAP study.

This study shows that additional qualitative interviews among parents and the nursing and (para)medical staff might provide important additional information about relevant outcomes for future research, such as infant comfort during admission. The outcomes of a randomized controlled trial with standardized questionnaires, should not be interpreted as the sole

outcome on which decisions of implementation are based. Outcomes during or shortly after an intervention, also seem of importance because the infant and parents might then experience the effect of the intervention most profoundly. The other outcomes of the current study (somatic and developmental outcomes of the infant at 1 and 2 years of age) will be discussed in another thesis and are of importance for a complete representation of effects.

Qualitative questionnaires and interviews can also be of importance to evaluate the specific experiences and needs of parents and nursing and (para)medical staff. The outcomes could provide information about which aspects of early intervention and NIDCAP are the least or the most important to implement if one would only want to implement some aspects of the NIDCAP.

Research implications: Cost analysis

The study described in this thesis only found small benefits of the NIDCAP on infant behavior. The Cochrane review of previous Developmental Care studies concluded that research needs to focus more on providing cost-benefits information [18]. The three center NIDCAP trial [6] and the study on the effect of NIDCAP by Fleisher [9] did find lower hospital charges in the NIDCAP group. However, a review on NIDCAP by Jacobs [19] discussed that the charges for developmental assessments, the salary for a developmental specialist and the costs for training should be taken into account when studying the effect of NIDCAP. The training costs are approximately 4.000 US$ per person. Furthermore, the NIDCAP program guide states that 2 salaried positions (2 FTE) should be assured for a developmental specialist and a developmental care nurse educator [25]. The labor-intensive characteristics of the NIDCAP training and observations and guidance can also be costly. During training, one needs to perform 20 observations and to observe 1 infant at the NICU biweekly or weekly from admission until discharge and one observation at the infants home [25]. Observations should be done weekly or biweekly and an observation (including writing the report) usually costs approximately a working day. Besides further research on other

possible benefits of NIDCAP, further research regarding these costs seems appropriate.

Methodological considerations: Study design

Although randomization seemed to have resulted in comparable groups regarding the parent and child characteristics, covariate analysis was done with the parent and child characteristics as covariates. This was done for a more precise estimation of the differences between the groups on the outcome variables. Some questionnaires were missing in the covariance analysis because parents did not fill in their age or educational level. For comparison, in the context of selection bias, we performed t-tests which resulted in approximately the same significant differences of the total sample and the sample in the covariance analysis. The non-significant differences were also non-significant in the two sample t-tests with the total sample. When calculating the mean scores of the scales the scale score was a missing value if more than 30% of the items were not completed. This was done to make sure that most aspects (items) of the construct were completed and the scale score still resembled the whole construct measured. Furthermore, we corrected for multiple comparisons, which increases the possibility of finding a significant difference, by using a $p<.01$ as the level of significance.

When designing a randomized controlled trial to explore the effect of the NIDCAP intervention, it seems impossible to make the intervention double blind. It is always clearly visible for parents and the nursing and medical staff to which study group infant belongs. The outcomes described in this thesis mainly depend on parent reports through standardized questionnaires and therefore could be influenced by some bias because parents know which treatment their child received. The visible aspects of the intervention were, however, also thought to be the main reasons for a positive effect on one of the outcomes, namely parental stress.

The inclusion of infants for the NIDCAP study in Sweden was stopped before the required amount of infants was reached because of a spill-over effect [12]. The inclusion of infants in the Swedish RCT study took longer than expected and spill-over effect occurred because nurses were convinced of the benefits

of NIDCAP and indicated feeling uncomfortable taking care of the control infants. Because we included infants born < 32 weeks admitted to a large NICU with two locations in the current study, we were able to include a large number of infants in two consecutive trials over only 4 years of time. Furthermore, because we did not implement NIDCAP at once but in two consecutive steps during the two RCT's and it was not an "all or nothing" intervention, we expect to have minimised to effect of spill-over. The absence of the nests and covers in the control groups in the first trial and the absence of the NIDCAP observations and guidance in the second trial were adopted and respected by nursing and medical staff for research purposes. Nursing staff did indicate feeling relieved when the inclusion for the trials was finished and all infants were allowed the same treatment.

In the Netherlands a cut-off point was formulated for the treatment of preterm infants which indicates that only infants born > 25 weeks of gestation receive active treatment. This results in a population of infants with a higher gestational age at the NICU's in the Netherlands compared to, for example, the USA. The NIDCAP observations and guidance might work best within infants born with a low gestational age. The two NIDCAP studies in Sweden, which used different inclusion criteria, showed a difference in effect from which the researchers concluded that the impact of the NIDCAP intervention on medical outcomes might be correlated to the degree of prematurity and the severity of illness [15].

Because the study design consisted of two consecutive RCT's it was difficult to compare the standard care control group in the first trial with the NIDCAP intervention group in the second trial, which might have led to additional information. The basic developmental care groups in both trials were also not completely comparable regarding the infant's health condition at birth (infants in the second phase had a better mean CRIB clinical risk score and higher birth weight). Furthermore, the basic developmental care groups in both trials were not comparable on certain outcomes while both groups had received basic developmental care.

Additional analysis showed that of the couples that completed the questionnaire at admission but did not complete the questionnaire at 1 year (of both RCT's taken together), the mothers had reported significantly (p=.013) more stress during admission compared to the mothers that completed both questionnaires. The stress of fathers during admission did not differ among the couples that did or did not complete the questionnaire at 1 year. This indicates that we lost the group of most stressful mothers. Further analysis within this group that was lost at 1 year, showed that the control and intervention groups in both RCT's had comparable maternal stress levels during admission (data not shown). We therefore concluded that the loss of the more stressed mothers had no large effect on the final results of our RCT's.

This study found a small effect of the NIDCAP intervention on competence behavior, which is only a part of the behavioral spectrum. In the context of multiple comparisons, one should be cautious when interpreting the significant differences. It might be difficult for interventions at the NICU to obtain statistical significant effects on outcomes that do not differ from the general population. Some outcomes correspond with problems that are primarily related to the circumstances of the preterm birth. For example, the health-related quality of life of preterm infants at 1 year was lower, compared to infant born at term [26] on the stomach, lungs and eating problems scales, which seem related to the preterm birth. Health-related quality of life was furthermore already optimal for most infants in both groups which does not leave much of a window of opportunity to improve quality of life. McCarton and colleagues [27] reviewed preventive interventions for low birth weight infants and suggested that many infants develop within normal limits and might never have the need for corrective intervention programs. In this context, competence behavior might be more easily improved. This seems to be a relevant outcome on which a positive effect was found in the current study.

The support by social worker is standard and equally available for parents from all social economic levels in the Netherlands. This Dutch study also showed that the effect of the NIDCAP intervention seems influenced by the

Dutch setting and circumstances (i.e. the transfer policy). This suggests that it is difficult to generalize results from NIDCAP intervention studies and meta-analysis as a guideline for implementation in other settings.

The study design described in this thesis also has its strengths. Two large randomized samples were obtained to measure the effect of both a basic form of developmental care and the more extensive NIDCAP intervention. Furthermore, most infants remained in the study during follow up at 1 and 2 years of age.

Practical implications

The evaluation of staff opinions in a Dutch NICU led to several recommendations for the implementation of NIDCAP or developmental care in a NICU, being: easy access to continuous and up to date information, continuous clinical lessons, practical guidance, a multi-disciplinary approach and a multi-disciplinary NIDCAP team. In addition, it is necessary to minimize the possible negative effects of NIDCAP on job conditions and possibilities to improve (time)efficiency should be reviewed. The applicability of these recommendations depends on the specific characteristics and available resources of the unit and it is therefore recommendable to evaluate the consequences and possibilities per individual unit. Secondly, the decrease in the difference in stress levels of fathers and mothers, with mothers experiencing more stress than fathers, suggests that during the implementation it is important to evaluate and stimulate the involvement of fathers.

The current study found improved competence behavior of infants that had received the basic elements of developmental care (standardized nests and incubator covers). The standardized nests and covers are easy to implement and the theory of the reduction of external stimuli by creating an environment comparable to the womb seems logical. However, when implementing aspects of developmental care, it is important to involve regional hospitals more to ensure the continuation of the special care and information for parents.

The extensive NIDCAP intervention improved the infant's social relatedness behavior. This finding seems to relate to the aspect of the NIDCAP 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. Parents and nurses furthermore indicated a visible improvement on the well-being of the infants that received NIDCAP during admission. However, the NIDCAP intervention also costs money and time and is labor intensive.

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 and experiences with NIDCAP reported by parents and personnel at the NICU, 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 thesis 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 can encompass the use of standardized nests and incubator covers and lower levels of sound, light and activity in the unit. In addition, some basic recommendations and clinical lessons on infant behavior, based on the NIDCAP observational tool and the synactive theory of infant development, need to be formulated. Evaluation of the importance and applicability of different aspects of the NIDCAP might lead to the development of a less intensive NIDCAP based intervention.

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