STRESS AND DISCOMFORT IN THE CARE OF PRETERM INFANTS

A study of the Comfort Scale and the Newborn Individualized Developmental Care and Assessment Program (NIDCAP®) in a Dutch level III NICU

For Thijs and all other preterm infants, unknown of the strain to stand on one's own feet in the outside world after their NICU stay.

Cover illustration: Drawing from Charlotte Haldewang, Mother of Gustave (2006)
A preterm infant looks a lot like a snail, vulnerable and needs to be approached with gentle care and likes to withdraw into the silence and darkness of its shell. The process of implementing NIDCAP is moving forward with the same speed as the snail. For those reasons the snail was chosen as the mark of recognition of the NIDCAP study.

The research in this thesis was performed at the Intensive Care Neonatology of the Emma Children's Hospital / Academic Medical Center, University of Amsterdam, in Amsterdam, The Netherlands

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Contents

Abbreviations

LIST OF ABBREVIATIONS

AABR	Automated Auditory Brainstem Response
BSDI-II	Bayley Scales of Infant Development-II
CLD	Chronic Lung Disease
CS	Comfort Scale
CPAP	Continuous Positive Airway Pressure
CV	Conventional Ventilation
CV	Conventional (group)
DC	Developmental Care
FTE	Full Time Equivalent
GA	Gestational Age
HFFI	High Frequency Flow Interruption
HFO	High Frequency Oscillation
HFV	High Frequency Ventilation
ICU	Intensive Care Unit
IPPV	Intermittent Positive Pressure Ventilation
IRDS	Idiopathic Respiratory Distress Syndrome
IVH	Intraventricular Haemorrhage
IWS	Index of Work Satisfaction
LHICN	Landelijk Hoofdenoverleg Intensive Care Neonatologie
MDI	Mental Developmental Index (BSID-II)
NBAS	Neonatal Behavioral Assessment Scale
NEC	Necrotizing Enterocolitis
NICU	Neonatal Intensive Care Unit
NICU-PSF	NICU- Parent Satisfaction Form
NIDCAP®	Newborn Individualized Developmental Care and Assessment Program
NONB	Naturalistic Observation of Newborn Behavior
NPST	Nurse Parent Support Tool
NTISS	Neonatal Therapeutic Intervention Scoring System
PDA	Patent Ductus Arteriosus
PDI	Psychomotor Developmental Index (BSDI-II)
PVL	Periventriculaire Leucomalacia
RN	Registered Nurse
ROP	Retinopathy of Prematurity
SGA	Small for Gestational Age
SIMV	Synchronized Intermittent Mandatory Ventilation

LIST OF STATISTICAL ABBREVIATIONS

ANOVA	Analysis of Variance
AUC	Area Under the Curve
CI	Confidence Interval
F	Parametric statistic representing differences in group means
ICC	Intraclass Coefficient
IQR	Interquartile Range
n	Number
ns	Not Significant
OR	Odds Ratio
P	Percentile
P	Probability Value
r	Pearson's r; product moment correlation coefficient
RCT	Randomized Control Trial
ROC	Receiver Operating Curve
SD	Standard Deviation
SPSS	Statistical Package for Social Science
t	Parametric statistic representing differences between two group means
U	Non-parametric statistic representing differences between independent samples
WK	Weighted Kappa
z	Standard Score

Chapter 1

Introduction

The last few decades perinatal and neonatal care has changed. Technological and pharmacological possibilities of treatment increased and existing treatments improved. The importance of these changes for preterm and critically ill infants and the impact on their clinical outcome and development has become a concern for the professional caretakers, neonatal nurses as well as neonatologists.

Epidemiology

In 2003, 13,547 of the 189,899 alive newborn infants (>24 weeks gestational age) were born prematurely (<37 weeks gestational age) of which 1904 infants were born very preterm (<32 weeks gestational age) in the Netherlands.[1] The Neonatal Intensive Care Unit (NICU) of the Emma Children's Hospital / Academic Medical Center is a referral unit for critically ill preterm and term infants. This NICU has also a regional function for older more stable preterm infants. In 2003 558 infants admitted to this unit needed intensive care treatment, 167 infants were born preterm and 186 very preterm[2].

Neonatal mortality (0-28 days) rates for very preterm infants in our NICU was 11% in 2003.[2] This is comparable with the overall neonatal mortality rate in the Netherlands in 2003 (14%).[1,3,4] In 1983 the overall neonatal mortality rate for this age group in the Netherlands was 31%, and in 1993 it decreased to 17%.[5-7] The decreasing mortality rates in the Netherlands are also seen in other European countries as well as in countries overseas.[8-13]

The most common disorder in (very) preterm infants is Respiratory Distress Syndrome (RDS). The incidence of RDS is higher when infants are more preterm or have a low birth weight (<1500 gram).[2] Treatment of RDS has resulted in the use of advanced ventilation techniques and pharmacological interventions (surfactant, steroids). Despite improvement of care the incidence of the most important pulmonary morbidity, chronic lung disease (CLD) have remained unchanged at about 22% of surviving preterm infants.[14] Infants with very low birth weight (501 to 750 grams) have a higher incidence of CLD compared to infants with low birth weight (1251-1500 grams), respectively 46% (range 25-81%) and 6% (range 2-23%).[14]

Another problem in the care of (very) preterm infants is the occurrence of intraventricular haemorrhage (IVH) and periventricular leucomalacia (PVL). Both occur more frequently in infants born below 1500 grams birth weight. The incidence of IVH overall determined by ultrasonography is approximately 27%, and 12% restricted to grades III and IV.[14-17] The incidence of PVL based upon ultrasonographic findings range from 1 to 5%.[14-17]

Preterm infants are at an increased risk for having infections during the hospital stay.[18-20] Overall, the risk is the greatest after the first week of life. Around 21% of very preterm infants develop a culture-proven sepsis, over 50% is treated for clinical or proven sepsis at least once during hospital stay.[18,21] A small number of infants develop meningitis (5%) and/or necrotizing enterocolitis (10%).[22]

A major problem in the care of preterm infants is instability of blood pressure; high and low blood pressure occurs frequently and is associated with cranial haemorrhages and periventricular leucomalacia, while the preterm brain is still immaturely developed and vulnerable. Hypertension can be induced by activities such as crying, body movement, feeding, and therapeutic interventions, including endotracheal intubation or suctioning.[23] Hypotension is often seen during severe infection or sepsis.[24,25] Fluctuations in systemic blood pressure during mechanical ventilation have been associated with the occurrence of IVH and PVL.[25,26]

Neonatal morbidity, as a result of pulmonary immaturity, intracranial events and infections in the preterm infant consequently affects morbidity later on in live. Almost 10% of all very preterm infants are diagnosed with severe handicaps before the age of five.[27] This percentage remains unchanged since 1960-1970. Around 50% of all preterm infants develop disabilities or impairments, measured at school age.[1-13,28-32] Comparison with healthy term peers results in a six times higher chance on impairments.[33] Initially it was thought that these infants would overcome their developmental problems when aging. However this appeared not to be the case. These infants demonstrate difficulties with attention, behaviour, visual-motor integration, language performance and/or academic skills.[5, 30-32,34-40] Overall optimal development and performance is seen in 31% of children born in 1983 of <32 weeks gestational age and in 41% of children born in 1993.[5,30,31]

Neonatal intensive care

Neonatal intensive care treatment and the environment of the neonatal unit have a major impact on the infants and hence their development. Intensive care treatment and caregiving activities cause a lot of pain and (di)stress apart from environmental disturbances like noise and light. This results in periods without rest and undisturbed sleep for preterm infants. Handling a preterm infant for more than 200 times per 24 hours is not uncommon.[41] Three out of four hypoxemic episodes are associated with caregiving itself.[42-46] Mechanical ventilation, a common treatment in the majority of these infants, is accompanied by a lot of potential stressful interventions like (re)intubation, endotracheal suctioning, punctures, skin lesions, and the use of adhesive materials. A-synchronized spontaneous breathing known as "fighting the ventilator" is a known phenomenon, therefore, the mechanical ventilation period can be described as a very stressful and uncomfortable period.[47-50]

Excessive handling is also a factor that encroaches upon the vulnerability of the brain. PVL and IVH are the result of impaired cerebral vascular auto regulation, which is needed to maintain adequate cerebral blood pressure when systemic blood pressure varies.[25] The number of invasive procedures infants undergo while in the NICU is staggering. A case described an infant born at 23 weeks gestation underwent 488 painful procedures during the NICU stay.[51] Other reports on invasive procedures mention between two and

ten procedures per day as well as an average of 53 moments of handling, lasting an average of 2.7 hours per day.[52,53]

Stress and discomfort caused by treatment and caregiving interventions are experienced during the long period of hospitalization of preterm infants. Although more immature in their responses, preterm infants are more sensitive to pain (stress) than older infants.[54-57]

Experiences of repeated and long lasting exposure to pain have been proven to result not only in acute physiological responses, but also changes in the structure and function of the brain.[58] One study has shown how developing pain circuitry depends on non-noxious sensory activity, and how early injury can alter pain processing permanently.[59] Besides, sensory input affects the synaptogenesis of neuronal networks and therefore the ability of the functioning of these networks.[36] Sensory input may easily over-stimulate very preterm infants during a critical period of extraordinarily rapid brain development. Stressful situations and repetitive stress in an early stage of life are a serious threat to the immature brain and consequently for later development of these vulnerable preterm infants.[50,58,60-63]

Development of the brain

Neural multiplication and migration in the germinal zone has largely been completed at 30 weeks of gestation. Astrocytes, however, are still being formed and migrating to upper cortical layers. During the same period myelinisation begins and naturally occurring apoptotic neuronal death is more frequent than at any other time of brain development. Up to 70% of the neurons in the human cortex undergo apoptosis between the 28th and 40th week of gestation.[64-66] The volume of the cortical grey matter normally increases almost four-fold from the 30th and 40th week of gestation.[64,67] The synaptogenesis of neuronal circuits is regulated by endogenous factors on one side and by sensory input and experience the other side.[68] Therefore, it is not surprising that the brain will be negatively influenced by preterm birth and all the consequences of undergoing intensive care treatment. Als described in a study that neonatal intensive care experiences before term age, influence brain development.[69] Early prolonged exposure to pain and stress is proposed as one of the contributing factors to later difficulties with self regulation and attention span in very preterm infants. [57,62,70,71] Self regulation, being a marker of neurobehavioral organization may predict later developmental outcome.

Stress

Stress, (di)stress and non acute pain are often used interchangeable in clinical practise as well as in literature. Stress can be described as the reactions of the body or mind to forces of a deleterious nature, and various abnormal states that tend to disturb the normal physiological or mental equilibrium (homeostasis). Stress, distress and (non acute) pain can result in discomfort. It is hard to decide when observing an 'uncomfortable' infant

whether the behavioural discomfort is caused by stress or pain. But it is clear that 'all pain is stressful, but not all stress is painful'.[72]

Management and evaluation of stress and discomfort as well as anticipation during the neonatal period are important components in the care of preterm infants.[47,50,73,74] Stress and discomfort is also of major concern to parents.[75] Neonatal pain assessment has received increased attention over the past two decades.[76,77] Although a number of pain assessment scales for preterm infants exist and have been tested as research tools, yet no perfect clinical scoring system exists. Up to now there was no objective way to differentiate between pain and (di)stress of preterm infants. For older infants and children the Comfort scale has been developed, an instrument to measure distress during the period of mechanical ventilation.[78]

As advances in neonatal care lead to a better survival of smaller and sicker preterm infants, attention has shifted towards neuroprotective care strategies and neurodevelopmental support, in an effort to improve developmental outcome.

Cue-based individualized care can enhance the preterm infants' potential for normal development, and reduce the negative effect of their stay in NICU. How to identify preterm infants behaviour becomes a very important challenge for NICU caregivers to learn. Preterm infants can not communicate verbally with caregivers, but communicate their needs and status through behavioural cues that may indicate wellbeing or stress. Changes in preterm infant behaviour can be used to identify pain and stress.[79-81]

In this context, developmental care interventions have been designed in order to create a NICU environment that minimizes stress experienced by the infant. Preterm infants need to be as comfortable and as free of pain (stress) as possible to grow and develop to their full potential.

Developmental care

Developmental care was introduced in the early 1980's and is described as a group of interventions designed to modify the NICU environment, so as to minimize the stress experienced by the preterm infant. A number of elements are included in developmental care such as modification of external stimuli (vestibular, auditory, visual, tactile), clustering of nursing care activities and positioning and swaddling of the preterm infant to provide containment similar to the intrauterine experience and to support the infant-family relationship.

Research has been performed on the influence of separate developmental care interventions on neurodevelopmental outcome such as kangaroo care, oral stimulation and non nutritive sucking and vestibular, auditory and visual stimulation and positioning. But also on outcomes such as weight gain, length of mechanical ventilation, physiological stress (heart rate, oxygen saturation), and length of hospital stay.[82-108]

The NIDCAP

In 1986 the first publication on a complete model of developmental care, called the Newborn Individualized Developmental Care and Assessment Program (NIDCAP®).[109,110] was presented. This model is based on the Synactive Theory of Development.[111] The theory describes the infant as a system consisting of five subsystems; autonomic, motor, state, attention/interaction and self regulatory system. The subsystems develop independently in each phase of development but are in constant interaction with each other and with the environment (including the family). Each infant has its own specific way of being interactive which can be observed as behaviour with the Naturalistic Observation of Newborn Behavior (NONB).[109,110] Prior to the NONB information on infants' location, bed, clothing, and bed space, ratings of nursery room sound, light and activity levels will be obtained. After the observation, information on the medical history and current status are collected. The observation measures the organization of behaviour and self regulation in a given environmental setting and a set of caregiving situations. The observation visualizes the way the preterm infant communicates with its environment. A NIDCAP trained person observes the infant for a 60-90 minute period. This includes a 10 minute pre-activity observation and at least a 20 minute post-activity observation period, during which the observer has no interaction with the infant. A caretaking interaction

Table I Naturalistic Observation of Newborn Behavior (N=85 items)

Autonomic Behavior (N=25)
Respiratory: regular, irregular, slow, fast, short pause, AA (long pause)
Color: jaundice, pink, pale, web, dusky, blue
Neurologic: tremor, startle, twitch face, twitch body, twitch extremities
Visceral/respiratory: spit up, gag, burp, hiccough, bowel movement grunt, sounds, sigh, gasp
Motor Behavior (N=36)
Limb and/or trunk movement: flaccid arm(s), flaccid leg(s), active flexed arm(s), postured flexed arm(s), active flexed leg(s), postured flexed leg(s), active extended arm(s), posture extended arm(s), active extended leg(s), posture extended leg(s), smooth movements arms, smooth movements legs, smooth movements trunk, stretch down, diffuse squirm, arch, tuck trunk, leg brace
Face: tongue extension, hand on face, gape face, grimace, smile, mouthing, suck search, sucking
Extremity specific: finger splay, airplane, salute, sitting on air, hand clasp, foot clasp, hand to mouth, grasping, holding on, fisting
State Behavior (N=13)
States: disorganized deep sleep, quiet sleep, drowsy, alert, active awake and sleep, organized deep sleep, quiet sleep, drowsy, alert, active awake and sleep
Attention and Interaction (N=11)
Fuss, yawn, sneeze, face open, eye floating, avert, frown, ooh face, locking, cooing, speech movement

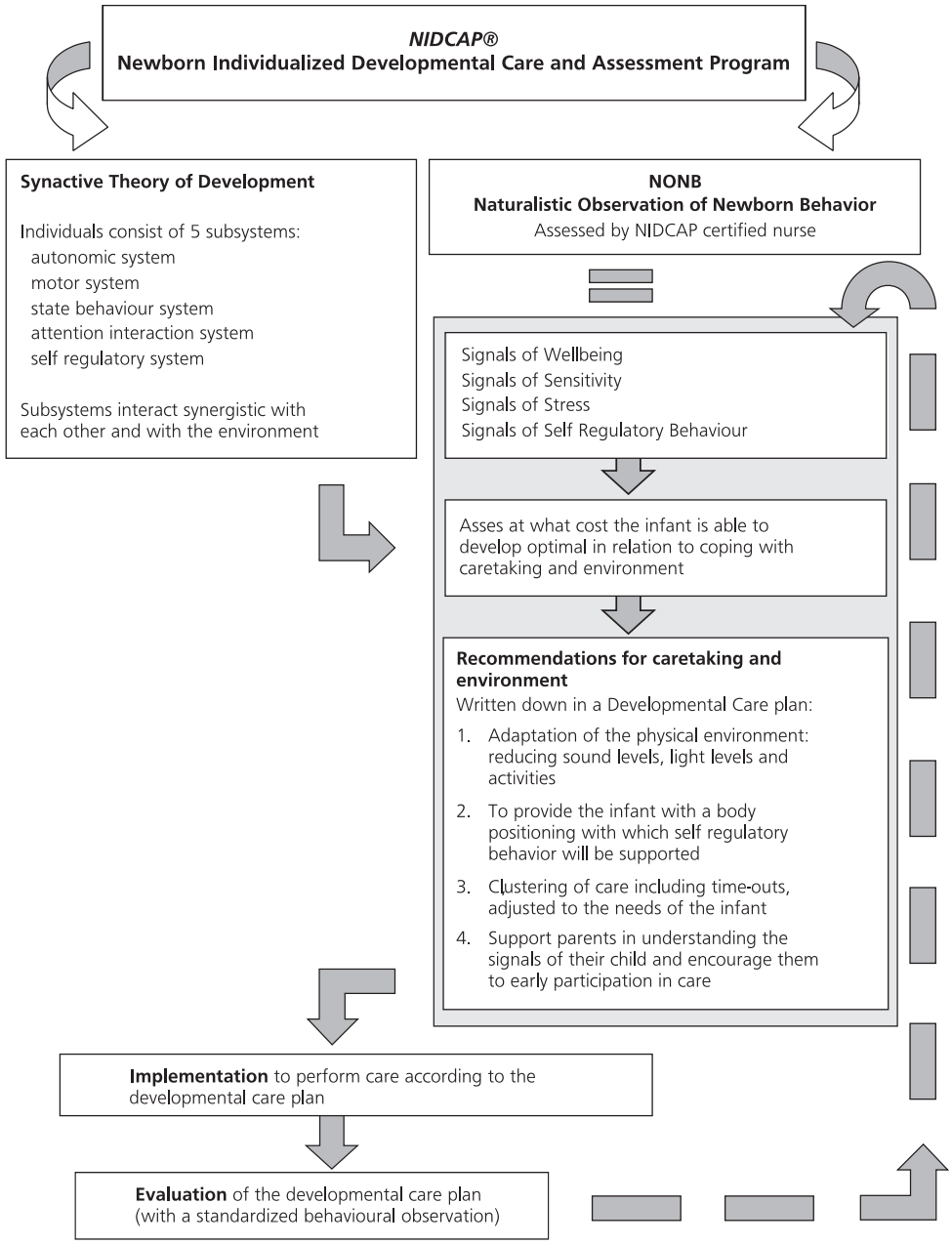
is observed like suctioning, diaper change, feeding session or blood sampling. The observation sheet is set up as a set of 85 items of behaviour which can be observed. This allows the continuous observation of the behaviour of the infant (Table I). Not the period of time a specific behaviour is shown but the frequency of appearance of a certain type of behaviour is noted. The observed behaviour can be subdivided into the five subsystems; autonomic, motor, state, attention/interaction and self regulatory system. Each system is divided in subcategories consisting of several items. Additional information on the posture of the infant, the kind of intervention or manipulation performed and vital parameters, such as heart rate, respiratory rate and oxygen level is noted. Following the observation, a case report is written assessing the infants' current ability to organize and modulate the five subsystems. The case report consists of several standard parts: introduction, description of the nursery environment, the behaviour of the child before, during and after caregiving interaction. The infants' behaviour described as, approach towards or avoidance of stimuli, enables the observer the possibility to assess how the infant strives to cope with the caregiving and the environment in order to continue its development. The observations provide information concerning the infants' strengths and weaknesses. Next a summary is written consisting of the medical history, the last 24 hours and the present behavioural functioning. Finally, current goals and caregiving recommendations to support the individual infants' development are formulated. Caregiving recommendations are then used by parents as well as professional caregivers to diminish stress and to support the infants' competence to overcome stress and discomfort (Figure I). This results in longer periods of restfulness and calm breathing, a well-functioning digestive tract, a well-modulated tone of the extremities, trunk and face, and a comfortable restful position. The tempo of caregiving procedures is individualized, slowed and adjusted in timing and well-supported relaxation periods are provided.

The information provided by the observation is used to individualize care and environment to the needs of the specific infant. In this way, after modification of external stimuli, clustering of care activities and positioning, individualization of care and family support is added as a fifth dimension to developmental care.

NIDCAP is believed to support the infants' development, with the structuring of the appropriate physical environment in the NICU for the infant and the family, the timing and organizing of nursing care and medical interventions appropriate to the individuality of the infant and the family, supporting and facilitating the parents' confidence in caring for their infants physical and developmental needs.

In the years following the first publications on the NIDCAP model several promising research publications on this new model appeared.[107,108,112-120] Some studies showed significant results in the outcome parameters, in favour of infants cared for by NIDCAP such as reduction in ventilation days[112,113], less IVH[113], increased weight gain[108,113], decreased days of parenteral feeding[112-114,116], better physiological stability[118] and behavioural organization[107,112-114], less complications [108,113,114] and decreased length of

Figure I NIDCAP Flow chart



hospital stay[108,113,114,116] as well as a better mental and psychomotor development up to the age of 12 months.[112,113] However, other studies were not able to show differences between infants cared for by NIDCAP or in a conventional way.[107,108,114,120]

Two systematic reviews were performed on NIDCAP.[121,122] Both reviews showed limited evidence of NIDCAP on moderate-severe chronic lung disease, necrotizing enterocolitis and family outcome (stress and perception). There was also very limited evidence for long-term effects on behaviour and motor outcome at five years and no benefits on cognition. The cost of intervention was considerable. The meta-analyses illustrated the large variation in outcomes and limited numbers of randomized control trials that were included in each outcome. The reviewers addressed a number of design limitations. Because of the nature of the intervention blinding was not possible, sample sizes were small, contamination of the intervention by existing developmental care practices and differences in gestational age of the infants included. The reviewers called for more (multi-center) trials with larger sample sizes to study the effects of NIDCAP. Recently, a group from Edmonton presented preliminary short-term outcome from a large NIDCAP randomized controlled trial on very low birth weight infants that confirms findings of significantly less mechanical ventilation, lower incidence of chronic lung disease and shorter hospitalization, as noted in the earlier smaller trials included in the systematic reviews.[123]

Despite the conflicting study results up to now, for the NICU of the Emma Children's Hospital / Academic Medical Center, with a long history of being interested in the humanization of the highly advanced technological care and a traditional interest in preventing stress and discomfort for newborn infants as well as in the parental involvement in the care and decision making process it was just a logical consequence to be interested in implementing such a practice in care.

Objectives of the study

In this thesis stress and discomfort and new ways of reducing stress and discomfort for preterm infants in the NICU, including consequences in infant outcome and the satisfaction of parents and nursing staff related to the care was subject of study. In more detail we studied the next objectives:

1. The Comfort scale can be validated to assess stress and discomfort of preterm infants.
2. The Comfort scale is useful in studying stress during different techniques of mechanical ventilation.
3. Care according to NIDCAP improves the clinical outcome during NICU stay of very preterm infants.
4. Care according to NIDCAP during the NICU period improves growth and developmental outcome during the first two years of life of very preterm infants.
5. NIDCAP increases the satisfaction rates of parents of very preterm infants.
6. NIDCAP improves the job satisfaction of nursing staff caring for very preterm infants.

Outline of this thesis

Chapter 1 of this thesis presents a general introduction including the objectives of the study.
In chapter 2 one of the major problems in the NICU, namely stress is described. Validating the Comfort scale to measure stress of ventilated preterm infants is presented.
Chapter 3 focuses on conventional and high frequency ventilation modes in the care of preterm infants and the consequences for the amount of stress experienced.
Chapter 4 describes the current status of developmental care and NIDCAP in Dutch speaking NICU's in the Netherlands and Flanders.
Chapter 5 compares the NIDCAP as a new model of care of preterm infants in the NICU with the conventional care model and evaluates its effects on medical outcome during hospital stay.
Chapter 6 describes the results of infants cared for with NIDCAP compared to conventional care on developmental outcome and growth in the first two years of life.
Chapter 7 presents the levels of satisfaction of the parents of infants cared for in the NICU in the NIDCAP way or the conventional way.
Chapter 8 outlines the job satisfaction of the nursing staff with the introduction of NIDCAP in the unit.
Finally, in chapter 9 and 10, a general discussion, conclusions and the summary of the main results of this thesis are provided.

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Chapter 2

COMFORT SCALE: A reliable and valid method to measure the amount of stress of ventilated preterm infants

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ABSTRACT

Objective Assessment of clinimetric properties and diagnostic quality of a stress measurement scale (Comfort scale).

Design Sample of an open population.

Setting Neonatology Department (Neonatal Intensive Care Unit), Emma Children's Hospital / Academic Medical Center, Amsterdam, the Netherlands.

Method One clinical expert and 9 observers observed ventilated premature born babies simultaneously. Criterion validity was assessed by correlating the Comfort scale with the clinical judgement regarding the amount of stress. Interobserver reliability was assessed on the clinical judgement as well as on the Comfort scale. Diagnostic qualities were evaluated with a ROC curve.

Results On 19 ventilated premature born babies (mean gestational age 30 weeks, mean birth weight 1385 gram), one clinical expert and 9 observers made 30 paired observations. The criterion validity of the Comfort scale was good (Pearson's r of 0.84). The interobserver reliability of the clinical judgement was very good (weighted kappa 0.84). The interobserver reliability of each item varied from good to almost perfect (weighted kappa of 0.64 for muscle tone to 1.00 on heart rate). The reliability of the total Comfort scale score was satisfying (intra-class correlation coefficient of 0.94). The diagnostic quality of the Comfort scale was excellent, at a cut off point of 20 the sensitivity was 100%, the specificity was 77%, and the area under the curve (AUC) of 0.95.

Conclusion In this first evaluation, the Comfort scale appears to be a valid and reliable measurement tool to assess the stress of ventilated premature born babies.

INTRODUCTION

Artificial ventilation is in most cases a very stressful event for new born preterm infants. Stress causes hormonal and metabolic changes and may have a negative influence on treatment.[1-3] On a short term base stress can result in a prolonged period of ventilation, more chronic lung damage, lower increase of bodyweight and a prolonged period of admittance to the hospital.[4,5] In the long run stress is associated with more physical complaints (headaches and stomach-aches) and a less appropriate motor and behavioral development.[2,4,6-10]

Stress during ventilation is caused by relatively short time procedures like endotracheal suctioning, but also by shorter or longer periods of asynchronous spontaneous breathing with the mechanical ventilation, so called "fighting the ventilator". Stress during ventilation is treated with sedatives and/or analgesia. Therefore it is important to find a right balance between on one side controlling stress, and on the other side administering the right dose of sedatives where the infant is still active enough to make a clinical judgement possible.

The problem of stress is increasing as more preterm infants are being ventilated. In 1993 at the NICU of our hospital 27% of all newborns were ventilated an average of 4 days and in 1999 the number had increased to 40% with an average of 8 days of ventilation.[11,12] Besides this increasing number, new modalities for ventilation became available. With the introduction of high frequency ventilation techniques, we observed an increase in the amount of stress in newborn preterm infants compared to those on conventional ventilation methods. To objectify this clinical finding we needed an instrument measuring the amount of stress and given sedation of ventilated premature born infants. A performed literature review provided us a few instruments for assessment of acute stress (pain)[13], but no instruments for assessment of prolonged stress in preterm infants. We found only one instrument for measurement of stress in older ventilated infants and children (0 to 17 years), the Comfort scale (Figure I).[14] With the purpose to validate the Comfort scale for the use in the NICU, we studied in ventilated premature born infants, the clinimetric properties of the instrument (interobserver reliability, and criterion-related validity) and assessed a first evaluation to the diagnostic properties (sensitivity and specificity).

PATIENTS AND METHODS

This study took place in the NICU of the Emma Children's Hospital / Academic Medical Center in Amsterdam, the Netherlands, from May until July 1997. During this period we selected ventilation dependent preterm infants with respiratory distress syndrome (RDS), infection or respiratory failure due to exhaustion. The preterm infants included were born at a gestational age of 37 weeks at most and were not older then five days on the day

Figure I Comfort scale

	COMFORT scale	Score
	ALERTNESS	
	Deeply Asleep	1
	Lightly Asleep	2
	Drowsy	3
	Fully Awake and Alert	4
	Hyper-Alert	5
	CALMNESS/AGITATION	
	Calm	1
	Slightly Anxious	2
	Anxious	3
	Very Anxious	4
	Panicky	5
	RESPIRATORY RESPONSE	
	No Coughing and No Spontaneous Respiration	1
	Spontaneous Respiration with Little or No Response to Ventilation	2
	Occasional Cough or Resistance to Ventilator	3
	Actively Breathes Against Ventilator or Coughs Regularly	4
	Fights Ventilator; Coughing or Choking	5
	PHYSICAL MOVEMENT	
	No Movement	1
	Occasional, Slight Movement	2
	Frequent, Slight Movement	3
	Vigorous Movement Limited to Extremities	4
	Vigorous Movements Including Torso and Head	5
____ /____	**BLOOD PRESSURE (MAP) BASELINE**	
	Blood Pressure Below Baseline	1
	Blood Pressure Consistently at Baseline	2
	Infrequent Elevations of 15% or More (1-3)	3
	Frequent Elevations of 15% or More (more than 3)	4
	Sustained Elevation ≥15%	5
____ /____	**HEART RATE BASELINE**	
	Heart Rate Below Baseline	1
	Heart Rate Consistently at Baseline	2
	Infrequent Elevations of 15% or More Above Baseline (1-3) during Observation Period	3
	Frequent Elevations of 15% or More Above Baseline (more than 3)	4
	Sustained Elevation of ≥15%	5
	MUSCLE TONE	
	Muscles Totally Relaxed; No Muscle Tone	1
	Reduced Muscle Tone	2
	Normal Muscle Tone	3
	Increased Muscle Tone and Flexion of Fingers and Toes	4
	Extreme Muscle Rigidity and Flexion of Fingers and Toes	5
	FACIAL TENSION	
	Facial Muscles Totally Relaxed	1
	Facial Muscle Tone Normal; No Facial Muscle Tension Evident	2
	Tension Evident in Some Facial Muscles	3
	Tension Evident Throughout Facial Muscles	4
	Facial Muscles Contorted and Grimacing	5
	TOTAL COMFORT SCORE	

of the study. Preterm infants with congenital or neurological diseases or complications were excluded.

For artificial ventilation a Dräger Babylog 8000 in the synchronized intermittent mandatory ventilation mode (SIMV) was used or the intermittent positive pressure ventilation mode (IPPV), the high frequency flow interruption mode (HFFI), or the Sensor Medics 3100A in the high frequency oscillation mode (HFO). Heart rate and arterial blood pressure were monitored by a Hewlett Packard-monitor (type 78834a). Sedation was given according to the present protocol: continuous intravenous infusion of morphine (commonly accepted in the neonatology as a sedative) of 0.25 mg/kg/day, after a loading dose of 0.1 mg/kg.

Clinimetric properties

Criterion-related validity was assessed by relating the scores on the Comfort scale to clinical judgement of stress. Scores on the Comfort scale are the observed variation of the 8 items (alertness, calmness/agitation, respiratory response, physical movement, blood pressure, heart rate, muscle tone and facial tension) on a 1 to 5 scale.[15] The total score is the sum of the 8 separate item scores (maximum 40), the higher the score the more stress. The Comfort scale is administered (duration ± 3 minutes) after a 2-minute observation of the premature born infant; for the assessment of the muscle tone the infant has to be touched.

The clinical judgement of the amount of stress during artificial ventilation was assessed with a 5-points Likert scale (1 = very quiet, not moving, 2 = quiet, now and than moving, 3 = moving calmly, 4 = distressed, agitated and 5 = very distressed or very agitated).

The procedure for assessing the criterion-related validity was as follows: seven neonatal nurses (observers-to-be) received two hour training by an expert in assessing the Comfort scale by an expert for which videotapes were used. During the study period ventilated, preterm infants were observed before daily caregiving, during a 2-minute period by one of the observers as well as by the expert, simultaneously. After the observation, the expert and the observer independently made notes of the clinical judgement on the amount of stress on the Likert scale and scored the items on the Comfort scale. In this way, paired observations from the clinical judgement and the Comfort scale were collected. The interobserver reliability of the clinical judgement of the observers and the expert and the interobserver reliability of the Comfort scale were assessed.

The diagnostic properties of the Comfort scale were evaluated by calculating the sensitivity and specificity for the different cut off points of the Comfort scale, the clinical judgement from the expert about the presence of stress, described on the Likert scale (score 4/5) was taken as a reference point.

Statistical analysis

As far as it concerns the clinimetric properties, the criterion-related validity was analyzed by assessing the Pearson's correlation between the clinical judgement and the total score

of the Comfort scale. The interobserver reliability of the clinical judgement of observers and expert were analyzed by using a weighted kappa. A weighted kappa [16] is calculated by assigning a weight (1 - [1/ number of categories - 1]) to the frequencies in each cell of a table of agreement, with the distance to the diagonal representing the optimal agreement. In general, a kappa of 1.0 is known to represent a perfect agreement and 0.8-1.0 as almost perfect, 0.6-0.8 as substantial, 0.4-0.6 as moderate, 0.2-0.4 as fair and 0.0-0.2 as slight agreement.[17]

The interobserver reliability of the Comfort Scale was described by a calculated weighted kappa on the item level and over the total score by an intraclass coefficient (ICC).[18] The ICC is interpreted in the same way as a weighted kappa.[17]

The diagnostic properties in terms of discriminative power were summarized and described in a receiver operating procedure; a ROC curve. This curve is a graphic representation of the relation between the sensitivity of the Comfort scale (rightfully classified as signs of stress) and 1-specificity (not rightfully classified as signs of stress) for the different cut off points of the test.[19] Because the relative seriousness of missing one diagnosis of stress, the optimal cut off point was appointed at a sensitivity of 100%. At a calculated area under the curve (AUC) of 0.5 the discriminated power is judged as moderate and at an AUC of 1.0 it is judged as excellent.

RESULTS

In the period May to June 1997, 19 preterm infants (10 boys, 9 girls) were studied; mean gestational age 30 weeks (range: 26 - 36 $^{4}/_{7}$ weeks) with a mean birth weight of 1385 gram (range: 675 – 3490 gram). Observations took place between the day of birth (day 0) and the fourth day of life. The number of observations varied from one to nine per observer. In total 30 paired observations were simultaneously performed. Clinical judgement was scored on the Likert scale, and the separate items and total score on the Comfort scale were noted.

Table I Clinical Judgement and Total score on the Comfort scale

Likert Score	Clinical Judgement frequency		Comfort scale range	
	expert (N = 1)	observers (N = 9)	expert (N = 1)	observers (N = 9)
1	1	1	13	13
2	14	12	13 – 19	14 - 20
3	7	10	17 – 21	14 - 21
4	7	7	22 – 25	20 - 30
5	1	0	32	-

The distribution on the score of the clinical judgement in relation to the total score of the Comfort scale is presented in Table I. In 8 out of 30 clinical judgements of the expert, a relatively great amount of stress (Likert score 4/5) was registered, a sign of not enough sedation, while at one observation the infant was very quiet and did not move at all (Likert score 1), a sign of excessive sedation. Median and range of the item scores and total score on the Comfort scale are presented in Table II. The median of each of the separate item leaned towards the center (2-3) of the possible range (1-5). At the item 'respiratory response' the category "fighting the ventilator" was not registered. At the item 'blood pressure' only the categories "blood pressure below baseline" and "blood pressure consistently at baseline" were registered and at 'heart rate' only the category "heart rate consistently at baseline" was found. At 'muscle tone' the two extreme categories "no muscle tone" and "extreme muscle rigidity" were not registered.

Table II Median and range of the item scores and total score on the Comfort scale (N = 30)

Item	Median (range) expert	Median (range) observer
Alertness	2 (1 – 5)	2 (1 – 5)
Calmness/Agitation	1 (1 - 5)	1 (1 – 5)
Respiratory response	3 (1 – 4)	3 (1 – 4)
Physical Movement	3 (1 – 5)	3 (1 – 4)
Blood Pressure	2 (1 – 2)	2 (1 – 2)
Heart Rate	2 (2 - 2)	2 (2 – 2)
Muscle Tone	3 (2 – 4)	3 (2 – 4)
Facial Tension	2 (1 – 5)	2 (2 – 5)
Comfort total score (max. 40)	19 (13 – 32)	18 (13 – 30)

The interobserver reliability of the clinical judgement between the expert and the nine observers was substantial to almost perfect (weighted kappa 0.84, 95% CI: 0.72-0.95).

The range of scores on the Comfort scale varied from 13 to 32 for the expert and 13 to 30 for the observers. The interobserver reliability of the Comfort scale items between the expert and the nine observers after 30 paired observations is presented in Table III. The weighted kappa varied from 0.64 (95% CI: 0.44-0.84) for 'muscle tone' to a maximum of 1.00 ('heart rate'); these values indicate that the interobserver reliability of each of the items is good to outstanding. Because we were dealing with repeated measurements under different circumstances, we also looked at the interobserver reliability of the first observation of the 19 preterm infants. These values did not importantly differ from the scores stated above (Table III).

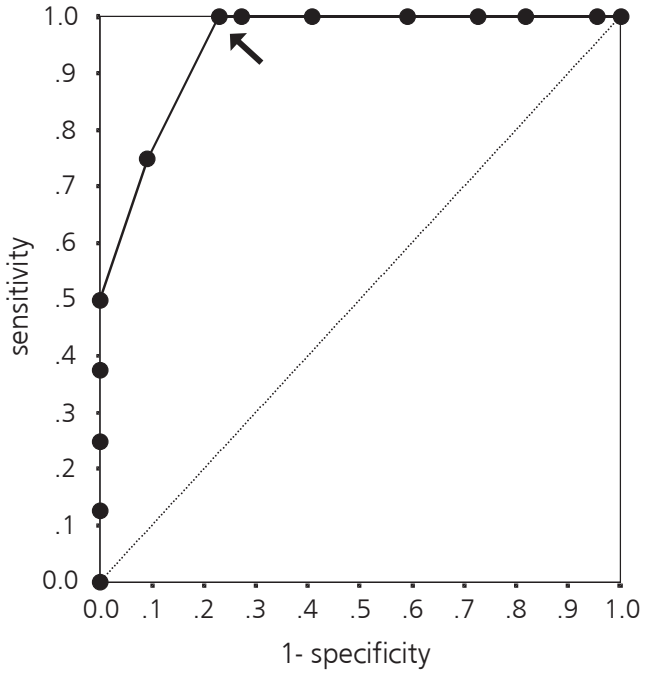
The interobserver reliability of the total score of the Comfort scale between the expert and the nine observers was almost perfect, ICC of 0.94 (95% CI: 0.85-0.98).

Table III Weighted kappa on the separate items of the Comfort scale and from Clinical Judgement after the first (N = 19) and total amount of observations (N = 30)

ITEM	(1st observation)		(total)	
	WK*	95% CI	WK*	95% CI
Alertness	0.96	0.88 – 1.00	0.93	0.86 – 1.00
Calmness/Agitation	0.86	0.77 – 0.98	0.87	0.73 – 1.00
Respiratory Response	0.79	0.57 – 1.00	0.71	0.49 – 0.93
Physical Movement	0.71	0.46 – 0.96	0.77	0.58 – 0.95
Blood Pressure	0.64	0.005 – 1.00	0.65†	0.02 – 1.00
Heart Rate	1.00			1.00
Muscle Tone	0.56	0.30 – 0.83	0.64	0.44 – 0.84
Facial Tension	0.85	0.71 – 0.99	0.81	0.65 – 0.96
Clinical Judgement	0.77	0.61 – 0.94	0.84	0.72 – 0.95

* Weighted kappa, † observed agreement of 93%

Figure II ROC curve



Cut off point	Sensitivity	Specificity	
20	1.00	0.77	(AUC 0.948)
21	0.75	0.91	
22	0.50	1.00	

The interobserver reliability of the total score of the first observations of the 19 preterm infants agreed with this (ICC of 0.95 at a 95% CI: 0.88-0.98). The criterion related validity, connecting the clinical judgement with the total score of the Comfort scale, was almost perfect (Pearson's correlation r = 0.84).

The diagnostic properties of the Comfort scale are presented by means of the ROC-curve in Figure II. At a sensitivity of 100% the specificity is 77% and the cut off point of the Comfort scale total score is 20. At a lower score it is not likely that the preterm infants suffer from stress while the Comfort Scale does not indicate that yet (excluding false negative rates). The (calculated) AUC was 0.95; this indicates that the Comfort scale at this cut off point in this population is able to discriminate well between preterm infants with and without stress.

DISCUSSION

The reliability and validity of the Comfort scale are previously assessed in a population of paediatric intensive care patients.[20,21] We found that the scale also met these clinimetric properties for ventilated preterm infants (Pearson's correlation 0.84 and ICC 0.94). The first evaluation of the diagnostic properties of the Comfort scale points out that the scale is able to discriminate between the presence and absence of stress (AUC = 0.95).

A few methodological aspects can influence a study like this. First, the choices of the point of reference to assess the clinical validity of the Comfort scale. It seems logical to take biochemical markers (adrenocorticotroop hormone / cortisol) as a reference point, but there are no general accepted reference points for these in relation to stress. In daily practice, these markers are not acceptable indicators because it takes several days between taking a sample and receiving the test results. Therefore, clinical judgement was taken as a reference point, using very experienced observers. Conscientiously we took a blinded independently comparison of the Comfort scale and carefully verified the interobserver reliability. For clinical judgement as well as for the Comfort scale we found very satisfying results (respectively 0.84 and 0.94).

A second aspect is making use of a convenience sample, with which so-called spectrum bias could occur. This means we unintended could have been selecting a specific string of ventilated preterm infants with a large contrast in the amount of occurring stress. The outstanding diagnostic quality (AUC 0.95) would be flattered in that case. In our opinion, this did not happen. After all, the prevalence of stress in our NICU was 27% (8 out of 30) which is very likely, taking the clinical judgement into consideration, whereby 15 preterm infants were classified as quiet to very quiet and 15 as moving calmly to very agitated, with few observations going into extremes. There is hardly any reason to suspect spectrum bias. However it is recommended, like any other diagnostic test, to further validate the Comfort scale in another setting and with another population.

The outstanding criterion-related validity (r = 0.84) makes it assumable that the Comfort scale is indeed measuring stress. Our study shows that most items use the whole range of scores and no ceiling or bottom effects occurred, except with the item of "calmness/ agitation" with a median of 1. The mean score of all other items are tending towards the middle, about 3, which is a desirable clinical situation. A low score can point out too much sedation was administered and will stand in the way of a clinical judgement of the level of consciousness, while a high score indicates serious stress.

Getting acquainted with the Comfort scale requires a training of about 2 hours. For this purpose we videotaped a ventilated neonate. Observers were trained by observing the infant on this video. During training it is desirable to give a few items of the Comfort scale special interest. For instance, the judgement of the muscle tone is not possible with the help of video records; one could practice this with a few healthy preterm infants. In our study, we at first found a difference in evaluation on how a normal muscle tone feels and how a decreased muscle tone feels.

In our NICU stress is a real problem; 8 out of 30 ventilated preterm infants have to deal with stress, despite the fact they received sedatives. This indicates the necessity of a good evaluation.

Clinical judgement has undoubtedly a great similarity with the Comfort scale items. In fact the Comfort scale is an explicitation of clinical judgement. Still, it is our opinion to prefer the Comfort scale for the evaluation of stress above clinical judgement. Because extended clinical experience is required to be able to come to a good clinical judgement of stress in preterm infants, sound clinical judgement is never guaranteed and never free from subjectivity. By using the Comfort scale, less experienced caretakers can also come to a good judgement of the amount of stress the infant is exhibiting. A very important property of the Comfort scale is that the score can be assessed without disturbing the preterm infant too much. After all, the scale uses observation: the infant is only touched just during the assessment of muscle tone. Making use of a non-intrusive objective observation fits very well in the stress-preventing policies of today's care of preterm infants in the NICU. The use of the Comfort scale takes little time, 2 minutes for the observation and 1 minute filling in the score, which can be easily integrated in daily caregiving of preterm infants.

More research with this promising instrument is necessary; however, the first results are encouraging. This first limited study indicates that the Comfort scale as a measurement tool for the amount of stress and sedation in ventilated preterm infants in a NICU is a useful, reliable, and valid measurement method.

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Chapter 3

Ventilation and stress in preterm infants; high frequency ventilation is not an additional stressor

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Pediatric Intensive Care Nursing accepted for publication

ABSTRACT

Aim To study the hypothesis that high frequency ventilation (HFV) is an additional stressor compared to conventional ventilation (CV).

Methodology A prospective explorative cohort study in a consecutive sample of 50 preterm infants (<37 gestational age) with Respiratory Distress Syndrome admitted to a Level III Neonatal Intensive Care Unit. During the first three days of ventilation stress was assessed by means of the Comfort scale (CS).

Results 35 Infants received HFV and 15 CV. The HFV group was significantly younger ($p = 0.003$), had a significant lower birth weight ($p = 0.017$) and were significant more severely ill ($p < 0.0001$). Stress scores between groups were comparable, adjustment for baseline differences revealed no differences in scores during the first 3 days of ventilation. Of all CS assessments, 34.0% in the HFV group and 35.6% in the CV group indicated stress (score ≥ 20).

Conclusion Stress during the first three days of mechanical ventilation using the CS did not reveal any difference between high frequency and conventional ventilated preterm infants. Routine use of sedatives seems insufficient to prevent high stress scores.

INTRODUCTION

Medical technology within Neonatology has strongly and rapidly developed the last two decades. A wider range of intense medical treatment became available and current ways of treatment are being improved and refined. The technical possibilities, such as mechanical ventilation strategies, often result in rather aggressive medical and nursing interventions. The period of mechanical ventilation can be described as a very uncomfortable and stressful period. [1-4] Notwithstanding the fact that it is difficult to prove that mechanical ventilation is painful or stressful in itself, mechanical ventilation is accompanied by a lot of potential painful interventions like (re)intubation, endotracheal suctioning, skin lesions as a result of punctures for blood samples, and change of adhesive materials. The less mature the infant the more likely the infant will be dependent of mechanical ventilation and the less mature the infants the more stress and painful procedures are performed. Infants of lower gestational age (GA) are known to be more sensitive to stress and pain.[5-8] Repetitive pain may lead to increased cell death in the immature brain, poor neurological outcome, abnormal behaviour as adolescents or adults and increased vulnerability to stress, anxiety and psychiatric disorders.[6,9-12] For all these reasons stress and pain should be prevented and minimized as much as possible.

Stress and pain are often used interchangeable in clinical practice as well as in literature. It is stated that all pain is stressful but not all stress is painful.[13]

With the introduction of high frequency ventilation (HFV) in the Neonatal Intensive Care Unit (NICU) of the Emma Children's Hospital / Academic Medical Center (EKZ/AMC), nurses reported an increase in stress in newborn infants. Nurses described stress in terms of discomfort, distress, agitation, restlessness, increase in pain and decrease in sleep time. Nurses had the impression that the constant vibrations of the HFV were an additional source of stress for preterm infants. Consequences of this constant vibration of the body are unknown.[14]

In the last two decades the number of ventilated infants increased from 27% for an average time of 4 days to 40% for an average time of 8 days. We wanted to study if HFV could be labelled as an additional stressor compared to conventional ventilation (CV) in preterm infants, during the first 3 days of ventilation.

METHODS

An explorative prospective cohort study with a convenience sample was performed. Infants born before 37 weeks of gestational age admitted to the level III NICU of the EKZ/AMC in Amsterdam, the Netherlands were consecutively included after informed consent. They were mechanical ventilated due to respiratory distress syndrome (RDS) confirmed by X-ray. Infants with congenital or neurological abnormalities and infants who

were ventilated later than 72 hours after birth were excluded. The study was approved by the Research and Ethics Committee of the hospital.

Clinical characteristics

Infant characteristics were collected on GA, birth weight, gender, and Apgar score at five minutes. Data on illness related characteristics included cerebral ultrasound findings (subependymal / intraventricular haemorrhage ≥ grade 1), air-leak syndrome (confirmed by X-Ray), sepsis (clinical symptoms and positive blood culture) or death. Treatment related characteristics were measured as therapy-based severity-of-illness by the Neonatal Therapeutic Intervention Score System (NTISS).[15] Infant characteristics, illness, and treatment related characteristics and the mode of ventilation were taken from the medical and nursing charts.

Procedure

Infants were ventilated in a CV mode (Dräger Babylog 8000) or in a HFV mode, either high frequency flow interruption (Dräger Babylog 8000) or high frequency oscillation mode (Sensor Medics 3100A). The choice of ventilation mode was made according to existing unit protocols; infants with a gestational age <30 weeks were preferably ventilated in the high frequency mode. Infants of ≥30 weeks gestational age were, if CV had reached a peak pressure of >24 cm H_2O, treated with HFV as rescue therapy. All ventilated infants were given a standard loading dose of 0.1 mg/kg morphine i.v. followed by a continuous i.v. infusion of 0.25 mg/kg/day morphine as analgesic therapy.

Outcome

Data on stress were collected during the first 3 days of ventilation by means of the Comfort scale, originally an instrument to measure distress in ventilated infants and children. Scores on the Comfort scale are the observed variation of 8 items (alertness, calmness/agitation, respiratory response, physical movement, blood pressure, heart rate, muscle tone and facial tension) on a 1 to 5 scale.[16] The total score is the sum of the 8 separate item scores (maximum 40), the higher the score the more stress. Prior to this study we tested the Comfort scale for its reliability and validity as well as its clinimetric properties in measuring stress in ventilated preterm infants.[17] The criterion validity of the COMFORT scale was good (Pearson's r of 0.84). Inter observer reliability of each item varied from good to almost perfect (weighted kappa 0.64 to 1.00). The reliability of the total COMFORT scale score was satisfying (intra class correlation coefficient [ICC] of 0.94). Based on the receiving operator characteristic (ROC) a score of 20 (giving a sensitivity of 100% and a specificity of 77% with an area under the curve of 0.95) was decided to represent the cut off point for stress.[17] The Comfort scale is administered (duration ± 3 minutes) after a 2-minute observation of the premature infant.

The first measurement of stress with the Comfort scale took place immediately after receiving informed consent. Next measurements of stress took place twice a day, before daily care procedures, during 3 days or less if mechanical ventilation was no longer needed. No interventions or handling one hour prior to stress measurement were performed. Observations were performed by observers trained in the Comfort scale.

Statistical Analyses

Results are expressed as means, standard deviation (SDs) for normally distributed variables and as medians and ranges in case of non-normal distributions. Chi-square statistics or the Mann Whitney U-test, when appropriate, were applied for group comparison. Subsequently stepwise multivariate linear regression analysis was employed to adjust the effect of mode of ventilation on Comfort scale scores for differences in clinical characteristics at inclusion. As numbers were small, only clinical characteristics that differed significant between both groups were introduced as independent variable next to mode of ventilation. All statistical analyses were performed using SPSS 12.0 software (SPSS, Chicago, IL, USA).

RESULTS

In the study period 65 of the 74 infants of < 37 weeks of gestation admitted to the NICU were eligible for the study. Parents of 56 infants were asked for participation; nine infants were missed due to an estimated short period of ventilation so informed consent could not be arranged before extubation. Six parents refused permission for various reasons; overwhelmed by the premature birth (2), the infant was to sick or too small (3), no reason mentioned (1). In total 50 parents gave permission by written informed consent.

The study group consisted of 50 preterm infants, 35 infants (20 boys) in the HFV group and 15 infants (12 boys) in the CV group (Table I). The HFV group infants had a statistically significant lower mean gestational age 28.7 ± 1.4 weeks, CV group infants were 31.3 ± 2.9 weeks ($p = 0.003$). Mean birth weight of HFV infants was statistically significant lower compared to CV infants, 1171 ± 337 grams versus 1585 ± 598 grams ($p = 0.017$). The HFV infants had a statistically significant higher mean NTISS score 27.6 points compared to 22.4 points of the CV infants ($p < 0.0001$). No significant differences were seen in Apgar score or gender. Illness related complications and medication were comparable between both ventilation groups (Table I).

Scores on the Comfort scale were comparable HFV and CV group infants at the start of ventilation, HFV mean 16.6 ± 3.6 vs. CV mean 17.7 ± 3.9, or at any of the separate ventilation days or moments (Table II). Comfort scale scores and the change over time of the scores are visualized in Figure I. A total of 274 Comfort scale scores were assessed during the study period of which 34.5% resulted in a score ≥ 20 points, indicating stress

Table I Clinical Characteristics of Study Infants

Characteristics	HFV (N=35)	CV (N=15)	p
Infant related characteristics			
Gender (m)	20	12	0.123
Mean birth weight (grams)	1171 ± 337	1585 ± 598	0.017
Mean gestational age (weeks)	28.7 ± 1.4	31.3 ± 2.9	0.003
Median Apgar score at 5 min	8 (0-10)	8 (2-10)	0.218
Illness related characteristics			
Complication present	42.9%	40.0%	0.529
≥ grade 1 cerebral haemorrhage	31.4%	33.3%	
Air-leak syndrome	8.6%	0%	
Sepsis (positive blood culture)	2.9%	6.7%	
Medication (analgesic/sedative)	100%	93.4%	0.458
Standard morphine	60.0%	66.7%	
Extra medication	40.0%	26.7%	
Treatment related characteristics			
Mean NTISS	27.6 ± 3.1	22.4 ± 2.7	<0.0001
Ventilation day 1	29.5 ± 5.1	24.4 ± 5.1	0.002
Ventilation day 2	26.7 ± 3.8	22.2 ± 2.0	0.001
Ventilation day 3	26.8 ± 3.2	19.4 ± 2.5	0.001

Values represent either mean ± SD or median and range, CV= conventional ventilation, HFV= high frequency ventilation, NTISS=neonatal therapeutic intervention score system

for the infant at that moment (Table II and Figure I). No significant differences were seen in percentages of scores ≥ 20 points HFV and CV ventilation, respectively 34.0% versus 35.6%.

Taking the significant clinical variables into account in multivariate analysis, no difference in stress was between both ventilation (mean difference [95%CI] HFV vs. CV: - 0.40 [-1.52 to 0.71] points, p = 0.475).

DISCUSSION and CONCLUSION

This study showed no differences in stress of preterm infants between HFV and CV. HFV was primarily given to lower birth weight, lower GA and sicker infants. Adjustment for these differences revealed also no differences in Comfort scale scores.

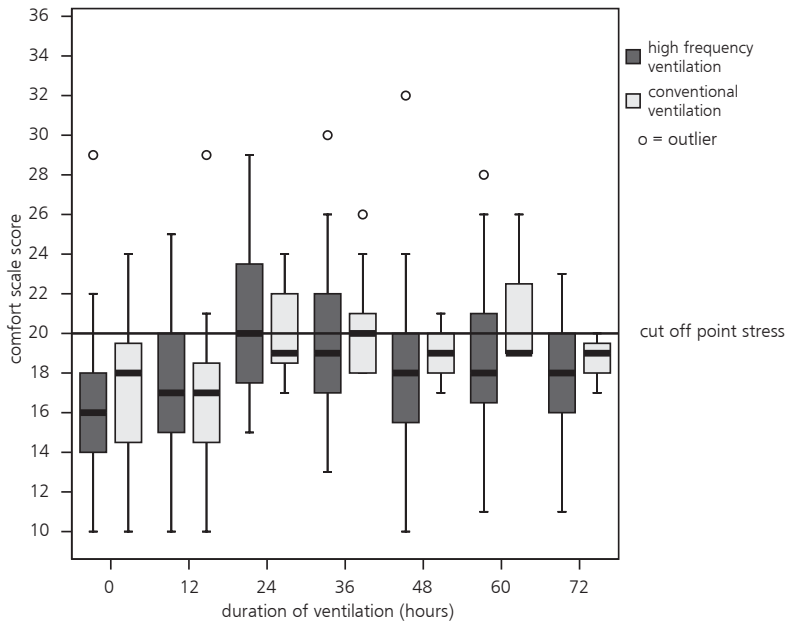
Research in the comparison of HFV with CV concerned the acute phase treatment, complications during treatment, long-term effects and refinement of the method and

Table II Comfort scale scores and percentage of infants with stress during first three days of ventilation

Time of Assessment	HFV			CV			p
	N*	CS mean ± SD	stress†	N*	CS mean ± SD	stress†	
Start of ventilation	35	16.6 ± 3.6	11.4%	15	17.4 ± 3.9	26.7%	0.237
Ventilation Day 1							
After 12 hours of ventilation	33	17.5 ± 3.6	30.3%	12	17.3 ± 4.7	16.7%	0.699
After 24 hours of ventilation	32	20.7 ± 4.0	59.4%	11	20.1 ± 2.5	45.5%	0.685
Ventilation Day 2							
After 36 hours of ventilation	31	19.3 ± 3.8	41.9%	10	20.3 ± 2.8	60.0%	0.344
After 48 hours of ventilation	29	18.3 ± 4.2	35.7%	6	17.4 ± 1.6	40.0%	0.434
Ventilation Day 3							
After 60 hours of ventilation	27	18.6 ± 3.9	33.3%	4	21.3 ± 4.0	33.3%	0.200
After 72 hours of ventilation	26	18.0 ± 2.9	26.9%	3	18.7 ± 1.5	33.3%	0.613
Total ventilation period		18.5 ± 2.1	34.0%		18.7 ± 2.1	35.6%	0.766

CV= conventional ventilation, HFV= high frequency ventilation, CS = Comfort scale score
* CS scores were omitted after extubation
† CS score ≥ 20 indicates stress

Figure I Comfort scale scores during the first three days of ventilation



Box plot illustrates the median, the interquartile range and the range that contains the central 95% of the Comfort scale scores for the HFV and CV group

technique of HFV.[18-22] Since we are the first to report on stress during HFV, comparison with other studies is not possible.

The present study concerned a non randomized comparison. Differences in clinical characteristics were accounted for in multivariate analysis. Control for unknown confounders is not possible with multivariate analysis and therefore it can't be ignored that they may have influenced study outcomes. This type of study can only be done as an observational study. The choice of ventilation mode is dependent on infant condition, and it is not ethical to randomize to one or another mode in order to study stress. However, stress could be included as a secondary outcome in a randomized study focusing on respiratory and or neurological outcomes.

Since study numbers were small, results need to be interpreted cautiously and need to be confirmed by larger studies. Next to a small sample size there was a wide range of gestational age, research in the field of stress is hampered by a still incomplete understanding of stress expression and behaviour in preterm infants of various gestational ages and factors that affect stress. Recently the Comfort scale has been modified to be used in for ventilated as well as non-ventilated infants with a gestational age of ≥ 35 weeks and a body weight of ≥ 1500g.[23] This adapted version has also been validated as a pain scoring tool for infants between 28 to 37 weeks during capillary blood sampling with interrater reliability 0.62 to 0.84 (weighted kappa) and ICC 0.92 (95% CI 0.89 - 0.96).[24] That study stratified for gestational age and found no differences in pain responses according to maturity.[24] However, the Comfort scale is not yet extensively tested to measure stress in preterm infants, the Comfort scale scores seem to be unaffected by maturity of the infant or ventilation mode.[17,24]

Our study took the edge off the impression among nurses that the impressive vibrations of the tiny bodies were an extra source of stress for the infants. Using the Comfort scale showed us that our "clinical look", concerning stress, was not accurate. Striking are the high percentages of scores ≥ 20 points (34.5%), meaning stress during the period of mechanical ventilation although this was not influenced by the choice of ventilation mode. The high percentage of stress could suggest an inadequate analgesic and sedation policy or could reflect the choice in cut off point.[17] A cut off point with a sensitivity of 100% results in a low cut off point and more false positive findings. Routine sedative medication as used in this study may have interfered with the Comfort scale scores. As the current use of analgesics and sedatives seems insufficient to prevent high stress scores a more effective analgesic and sedative policy during ventilation is needed.

In the near future we plan to study mechanical ventilation and stress with a randomized allocation to routine use of morphine or morphine based on stress scores. Hopefully, that study will provide us with a more adequate analgesic and sedative protocol for preterm infants during the period of mechanical ventilation. In the mean time it is recommended to assess stress, by means of the (adapted) Comfort scale on a routine basis during mechanical ventilation and provide non-pharmacological pain interventions next to routine medication.

Next to measurement of stress, ways to prevent and reduce stress of preterm infants in a period of life in which the brain development is so important have to be explored.

A study on Newborn Individualized Developmental Care and Assessment Program (NIDCAP®) could be highly relevant and worthwhile. [25] NIDCAP is known as a method to assess (stress) behaviour of the preterm infant at an individual level. Adjustment of care and the individual appropriate interventions are provided to prevent stress and to enhance comfort.

In conclusion; there is no difference in stress, as measured by means of the Comfort scale, during the first three days between HFV and CV in very preterm infants.

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Chapter 4

Developmental care in neonatal intensive care units in the Netherlands and Flanders

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ABSTRACT

Aim To gain insight into the current practice concerning developmental care in Dutch-speaking Neonatal Intensive Care Units (NICU).

Method In 2005 a survey was performed among 19 NICU's in the Netherlands and Flanders (Belgium). For this survey a questionnaire was designed and used. The questionnaire consisted of five domains: Principles of Care, Concept Clarification, Facilities and Resources, Professionals and Expertise, Research and Future.

Findings The response was 100%. Eighteen out of 19 NICU's reported the use of developmental care principles. There was an overall consensus on the definition of developmental care. The outline of the concept as well as the availability of facilities and materials showed great diversity. Four NICU's had caretakers with a high degree of expertise and special training (NIDCAP certified). In 18 out of 19 NICU's general developmental care education was provided. In five NICU's developmental care or aspects of developmental care were object of a scientific evaluation.

Conclusion In Dutch speaking NICU's there is a continuum of developmental care. Developmental care is applied in 3 different ways: 1. individual developmental care initiatives from caretakers; 2. developmental care with the availability of materials, facilities, management support and unit policy for developmental care; 3. developmental care according to NIDCAP principles which is characterized by care that is individualized based on behavioural observation and available know-how.

INTRODUCTION

Developmental care (DC) received a lot of attention being the model of care in Neonatal Intensive Care Units (NICU's) in a substantial number of countries around the world the last five years. These changes within the nursing profession are due to the changes within, the medical, technological, pharmacological developments and insights within neonatology. These developments have contributed to the decrease in mortality among newborn infants in the NICU (from 30% in the late eighties to 11% in the late nineties). However morbidity rates (40%) did not decrease as a result of these developments.[1,2]

DC was first introduced halfway through the eighties.[3] DC is the umbrella term for the type of care taking in account the environmental aspects of the NICU and the activities of caretakers to reduce the experienced stress by premature or sick newborn infants as much as possible. In contrast to environmental intrauterine circumstances the NICU stay is characterized by a large amount of (potential) adverse circumstances like excessive light and sound and uncomfortable activities with a lot of pain and stress and few moments of rest. These circumstances and routine nursing care causes the newborn infant to spend unnecessary energy and may influence growth and development in a negative way.[4-9] Moreover, the brain of the newborn infant which is in a critical phase of development is extremely vulnerable to stress.[10,11] Stress, pain and discomfort are known factors influencing medical and developmental outcome of newborn infants.[2-14] Therefore it is advisable to prevent or minimize these factors.

Developmental care strategies consist of one or more of the following aspects: decreasing external stimuli (vestibular, auditive, visual, tactile), clustering nursing care activities, positioning (body posture), providing boundaries and limiting environmental space in a attempt to imitate the intrauterine experience, and support the relationship between the newborn infant and his parents.[15-19] Next to these general strategies, programs exist for a more individualized approach and care of newborn infants. The Newborn Individualized Developmental Care and Assessment Program (NIDCAP®) of Als[3,20] is the most well known. This program uses structured, formalized observations (Naturalistic Observation of Newborn Behavior, NONB[3,20]) of the newborn infant' behavior, before, during and after caretaking activities. The infants' behaviour, described as approach towards or avoidance of stimuli, enables the observer the possibility to assess how the infant strives to cope with the caregiving and the environment and continue his development. These observations provide information concerning the infants' strengths and weaknesses. Subsequently, based on the observation, recommendations are formulated and given with respect to caregiving and environment to support the individual infants' development. These recommendations are used by the professional caretakers as well as the parent(s) or other caretakers. The parents have there own, fully integrated, place in the caretaking team and process.

Up to now studies concerning developmental care strategies are not showing consistent results. A recent meta-analysis concluded possible advantages for the preterm infant regarding decrease of chronic lung disease, decrease in incidence of necrotizing enterocolitis and improving outcome on parental stress and perception.[21] Studies showed limited evidence for improvement of behavior and movement up to 5 years of age as well. More research of developmental care strategies remains necessary.

Besides English speaking countries (United State of America, Canada, Great Britain and Australia), France and Sweden both have a long history concerning DC. At the end of the nineties DC became a topic in Dutch speaking NICU's as well.

After a slow start, gradually DC is far more reaching. Not only are NICU's interested in DC but also the neonatal units in non teaching and referral hospitals.

As mentioned before DC is an umbrella term for models of care, programs and strategies which have manifested in several ways.

In 2005 the national consultative body of NICU nurse managers (Landelijk Hoofdenoverleg Intensive Care Neonatologie, LHICN), which consists of nurse managers of all, ten Dutch NICU's, did not have a clear overview of the development of DC. It was decided to perform a nation wide survey, to conclude if new (nation wide) policy concerning organizational changes was necessary.

It appeared that the same need applied to the colleague nurse managers of the Flemish neonatology taskforce in Belgium. It was therefore chosen to perform a uniform survey in the Netherlands as well as Flanders to gain insight into the current state of Developmental Care.

METHODS

In the beginning of 2005 a survey was performed. All NICU's in the Netherlands and Flanders with Dutch as the official language (N=19) were included. In the Netherlands there are ten NICU's, one in each of the eight academic centers (Amsterdam [2], Groningen, Leiden, Maastricht, Nijmegen, Rotterdam and Utrecht) and two in regional centers (Veldhoven and Zwolle). Belgium has nine Dutch speaking NICU's, four in an academic center (Antwerpen, Brussel, Gent and Leuven) and five in regional centers (Antwerpen, Brugge, Genk, Rocourt and Wilrijk).

A specially designed questionnaire was used. The questionnaire existed of 16 questions, mainly dichotomy questions (yes/no) with space for further explanation (13) and some open questions (3). The questionnaire covered the following domains; Principles of Care (4), Concept Clarification (3), Facilities and Resources (3), Professionals and Expertise (4), Research and Future (2).

Content, wording (accuracy and legibility) and format were screened by a developmental care expert (NIDCAP certified) and a scientific researcher.

The questionnaire with an accompanying letter was sent by email to the nurse managers of the NICU's, requesting them to complete and return the questionnaire within three weeks.

All statistical analysis were performed employing SPSS 11.5.1 software (SPSS, Chicago, IL, USA).

RESULTS

All 19 NICU's (100%) have completed and returned the questionnaires within the appointed time schedule. The questionnaire was completed by different professionals; nurse manager (7), specialized nurse (5), nurse educators (3), nurse specialist (1), managing nurse (1), quality care nurse (1) and nurse researcher (1). The results present a summary of what respondents stated or reported.

Results questionnaire per domain

Principles of Care

In 1996 DC was first seen in one of the Flemish NICU's. In 1998 and 1999 two other NICU's followed. Most of the NICU's in Flanders (5) reported the gradually introduction of DC and were not able to indicate the exactly moment of time. In 1999 DC was introduced in the Netherlands in two NICU's. Other NICU's followed in 2002 (2), 2003 (1) and 2004 (4).

In 2005, 18 out of the 19 NICU's stated to perform care based on DC. Nine of these NICU's said to only perform DC partially. In the one NICU that did not use DC principles this was not based on principal choices. Four NICU's performing DC, had chosen to implement NIDCAP as the model of DC. Five NICU's made use of parts belonging to NIDCAP. The other nine had given their own interpretation to DC.

Concept Clarification

The NICU's had different thoughts about DC. All NICU's said they see the newborn as an unique being indissoluble bounded with his family. The proposed DC definition of Wielenga was fully acknowledged by 18 of the 19 NICU's, *"The individual care, focused on the development of the infant is a way of caretaking directed on comfort, stability, decreasing stress for the newborn and supporting and stimulating the relation of the newborn infant and his parents"* (internal publication, 2004). One NICU said that stimulating the relation between parent and infant belongs to another area (Video Interaction Support) and not to DC. In 13 out of 19 NICU's DC was used in a general way. Six NICU's made use of behavioural observations to be able to fine-tune DC to the needs of the individual infant. The most frequently behavioural observation was the

observation belonging to the NIDCAP, the NONB (4). Two NICU's used 'own' observation instruments.

Facilities and Resources

The way in which NICU's outlined DC in their unit and the consisting components were diverse. The NICU's pointed out that adaptations of the physical environment as well as new unit policies had taken place. In three NICU's furniture and equipment were adjusted to be able to guarantee DC. Six NICU's had developed policies regarding DC. Seven NICU's had extended the possibilities and facilities for parents. Four NICU's reported hardly anything had been adapted neither regarding the environment nor in unit policy. These units said they would take DC into consideration for future reconstruction plans.

Two of the NICU's had small individual rooms instead of the traditional large units. All NICU's had taken a series of actions to abandon unwanted stimuli, coming from light, sound or activities. Mentioned were reducing light by adapting the lightning (14), by using (bed) curtains or incubator covers (19) and/or investing in awareness concerning light, sometimes accompanied with measurements of light (6). As sound reducing actions were mentioned; decreasing sound levels of monitor alarms (12), no longer playing music in the NICU's (7) and creating awareness through the measurement of sound (6). One of the NICU's said they prevented unwanted stimuli by the use of background music. Daily visits of doctors had been transferred to a location outside the unit in two NICU's. One of the NICU's prevented unpleasant stimuli resulting from activity by using fixed rounds for caretaking, checking vital signs and for sleeping activity. Mostly using the ability of the infant as a starting point for care resulted in the letting go of fixed caretaking schedules and performing routine activities were mentioned in the other 18 NICU's. Minimize negative stimuli resulting from medical or nursing care activities through containment of the infant by a second caretaker was always the case in two NICU's. In 16 NICU's one tried to contain the infant during stressful and painful situations but not during uncomfortable situations. A remark was added; containment only took place when time and space was available. NICU's indicated containment depended highly on the individual nurse in charge of the infant. One NICU said they never ever contain the infant but they do assist with medical interventions. For containment a second nurse (18) was used, or a trained "container" with a nursing background (1), one of the parents (4) a medical, pedagogical- or civil assistant (3).

NICU's used special DC materials. In 17 NICU's materials were used for the support of the body posture such as, rolls (commercial or self made), a beanbag and (gel) cushions. Nests for the preterm infants to limit the environmental space and to support the body posture were used in 16 NICU's. In 11 NICU's soft stuffed animals, dolls and cloths were used to shield off the infant or to offer him something to hold on to. All NICU's used special dummies for preterm infants. Special, smaller good fitting diapers for preterm infants were used in three NICU's. Three NICU's indicated to have hardly any DC material available.

Professionals and Expertise

Four out of 19 NICU's had the availability of professionals specially trained in DC. In all cases this was the NIDCAP training. Not only nurses were trained but also physical therapists, psychologists and medical doctors. Eight of the other NICU's had organized a study day or specific education on DC from a NIDCAP point of view. Professionals used different sources to become informed on DC; clinical lessons (12), information provided by a study group on the unit (13), attending seminars (4), visiting other units (6), gathering articles (6), bedside teaching (4), through the training in neonatal nursing (3) and reflection sessions (1). One NICU said: DC was just a matter of using your common sense and education or training was not performed nor needed. Two NICU's did not answer the questions on training and information.

Research and Future

Five NICU's were performing a scientific evaluation of the DC concept or parts of the DC concept. The evaluations took place by nurses often in collaboration with medical doctors, psychologists and physical therapists. These five (Dutch) NICU's were performing the following studies; two NIDCAP implementation studies, one NIDCAP effect study, one study on a separate component of DC, the so called effect of "hands-on", and making DC procedures evidence-based.

Two NICU's preferred to wait for study results of previously mentioned studies before expanding DC activities. Continuation and expansion of implementation was the future plan of 10 NICU's. Of those 10, five NICU's would send professionals to special education and training facilities. Also mentioned as plans for the future were adaptation of policies and writing concrete plans for the future (8), starting standardized and individualized observations of behavior (3), architectonic adaptations (4) and establishing (inter)national collaboration (1).

CONCLUSION AND DISCUSSION

This study shows that DC is on the move in Dutch speaking NICU's. There seems to be a consensus about the definition of the concept of DC as described by Wielenga (internal publication, 2004). The DC concept is broadly accepted; the stage of development and the way it is carried out (general form of DC or the individual geared DC form) are very diverse. It is desirable to use the consensus on the DC definition as the starting point in the process of gearing the DC view and content within the different NICU's.

At this moment there are a lot of differences in NICU's working with DC. In the process of implementation roughly three types of DC are distinguishable within a continuum. Two turning points are responsible for this triad (Figure I). At the beginning of this continuum are the NICU's positioned using some of the principles of DC based on initiatives of

individual professionals. These NICU's don't have a policy formulated. In a second group, the first turning point, are the NICU's where the concept of DC is broadly accepted. DC exists of a set of resources and is part of the unit policy, meaning availability of facilities and support of the organization. The third group of NICU's, second turning point, have committed themselves to DC according to NIDCAP trying to establish individualization of care based on behavioral observations. This group has a high level of expertise present. Some of the NICU's pointed out to belong to one of the groups but based on their answers it became obvious that they belonged to another group within the continuum. Some NICU's talk about working with NIDCAP (9), but only four of them actually use the behavioral observation which is an essential part of NIDCAP and legitimizes the use of the term NIDCAP. What one does or says is not always congruent with reality. It is not clear if this is caused by the way the concept is handled, as a result of confusion concerning the clarification of concept, or just by the wish of a unit to perform NIDCAP while the unit is not yet ready for NIDCAP. The different outlines of the DC concept result in confusion and make it hard for NICU's to be able to reflect their findings to each other. Mutual comparisons are not possible in this way.

DC in whatever way does not only have consequences for the view and policy on care but also on the care process and the professionals, their expertise and the collaboration with other disciplines and parents. The nursing role changes, the nurses add another dimension to their expertise. DC also leads to changes in the way that NICU's are traditionally designed and organized. The end point on the DC continuum desired can be decided by each NICU individually.

LIMITATIONS

The disadvantages of questionnaires as used in this study may possibly have lead to sociably desirable answers. A personal interview and visit enables one to verify answers and to be able to ask for more explanation. Commonly, questionnaires are rather superficial and there is always the risk of an incorrect interpretation of the questions. Questionnaires do have some advantages compared to personal interviews, low costs and prevention of interviewers' bias.

Due to the fact that all Dutch speaking NICU's were participating in this survey, it was not possible to test the questionnaire and detect shortcomings of the questionnaire before the study. The possibility that respondents of this survey gave a more positive view of the reality of DC activities in their NICU's can not be excluded.

RECOMMENDATIONS

The first recommendation for the future is to organize a consensus meeting with all Dutch speaking NICU's to prevent confusion resulting from differences in the outline of the DC concept. It is important for the terminology to be used universal, relating to the outline of the DC concept as well as the description of types of DC and the place within the continuum. It would be of interest to perform this survey again after such a

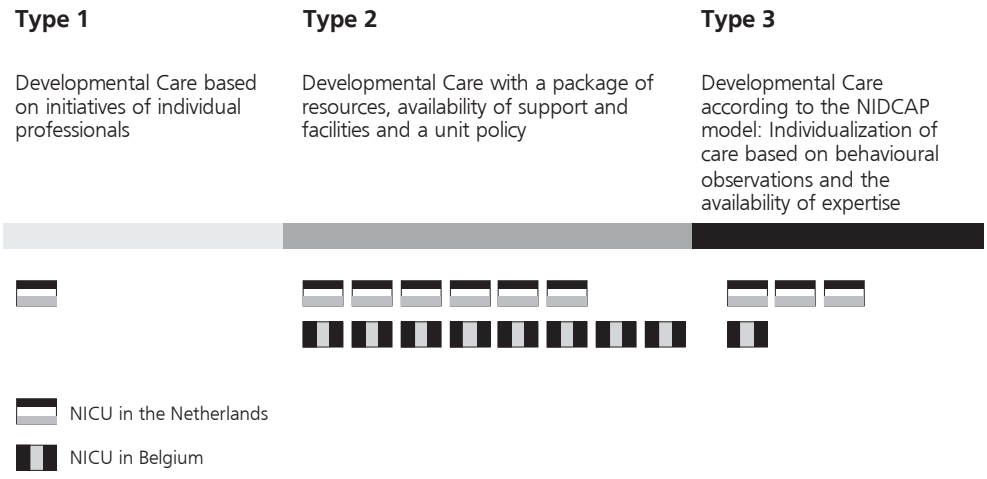
consensus meeting. It is recommended to include the results of the scientific studies on implementation and effect performed at this moment, as well.

The second recommendation concerns the use of the available expertise and knowledge of NICU's who are already on the right side of the continuum (Figure 1) by NICU's still more on the left side of the continuum. A model of site visits could be a way to give recommendations regarding DC policies, practical outline and necessary expertise to develop DC into a higher level, all based on the ambition of the NICU's being visited.

A third recommendation concerns the localization of DC in Dutch speaking NICU's compared to developments in foreign speaking NICU's. Comparison of the current practice in the Netherlands and Flanders with the practice of DC in other countries could make the international position of Dutch speaking NICU's visible.

The NICU's participated in this study are all speaking the Dutch language, but it appears these NICU's do not speak the same language talking about Developmental Care.

Figure I Continuum of Developmental Care



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Chapter 5

Individualized developmental care in a Dutch NICU: short-term clinical outcome

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ABSTRACT

Aim To compare the short-term clinical outcomes of NIDCAP® (Newborn Individualized Developmental Care and Assessment Program) and conventional care.

Methods A prospective phase-lag cohort study was performed in a Dutch tertiary level neonatal intensive care unit (NICU). Infants born before 30 weeks of gestational age (GA) were included, 26 in the conventional and 25 in the NIDCAP group. Outcomes were respiratory status, cerebral ultrasound findings, growth and length of NICU stay.

Results At study entry NIDCAP infants had a lower birth weight (mean [SD] 1043 [191] vs. 1154 [174] grams, p = 0.044), were more often small for GA (8 vs. 2, p = 0.038), had smaller head circumferences (mean [SD] 25.1 [1.3] vs. 26.1 [1.8] cm, p = 0.041), and were less often multiples (6 vs. 14, p = 0.029) than conventional care infants. During NICU stay more infants in the NIDCAP group developed pneumonia (9 vs. 3, p = 0.040), due to nosocomial infections. After adjustment for these differences a decreased risk for more severe cerebral damage in favour of NIDCAP was seen (Odds ratio: 0.12, 95% CI: 0.03-0.46, p = 0.002). No differences were observed for the other outcomes.

Conclusions We conclude with precaution that in this phase-lag cohort study NIDCAP may have resulted in less severe cerebral damage but was not associated with other clinical outcomes. In light of these findings NIDCAP deserves further exploration.

INTRODUCTION

The brain of preterm infants is still immature and rapidly developing in the neonatal and post neonatal period.[1,2] The Neonatal Intensive Care Unit (NICU) environment, with its constant noise, light, procedures and activity, is completely different from the intrauterine environment. Several studies on the effect of the stressful NICU environment on developmental outcome showed that the sensory impact of the NICU adversely affects maturation and organization of vision, hearing, sleeping pattern, growth and consequently neurodevelopment.[3-6]

The focus of care for very low birth weight infants has shifted from lowering mortality to improving outcome in the last decades. Therefore, developmental care interventions have been designed in order to create a NICU environment that minimizes stress experienced by the infant. The Newborn Individualized Developmental Care and Assessment Program (NIDCAP®) involves sequential, formalized, naturalistic observations of the infant's behaviour.[7,8] Caregiving recommendations are formulated to diminish stress and to support the individual infants´ competence and development.

Two systematic reviews found limited evidence for the benefit of NIDCAP on ventilatory support, chronic lung disease (CLD), length of hospital stay and costs, and neurodevelopmental outcomes at 24 months corrected age.[9,10] No major adverse effects have been reported.

As medical, socio-economic and cultural circumstances differ between units in different countries and even between units within one country, the objective of the present prospective study was to implement NIDCAP® and to compare short-term clinical outcome with a control group in the pre-implementation period in our tertiary NICU.

PATIENTS AND METHODS

A prospective, phase-lag cohort study was performed. In the first phase, a cohort of neonates receiving conventional care was enrolled, and assigned as the control group. This phase was followed by a NIDCAP introduction phase during which five nurses were NIDCAP trained and certified as NIDCAP observers. All other NICU nursing and medical staff was introduced in theoretical principles and practical skills necessary to be able to apply the NIDCAP intervention.[11] After this introduction phase, a second cohort of neonates receiving NIDCAP was enrolled. (Figure I)

Infants born before 30 weeks of GA and admitted to the level III NICU of the Emma Children's Hospital / Academic Medical Center in Amsterdam, the Netherlands, were consecutively included within 3 days after birth after parental informed consent, between August 2001 and January 2002 (conventional care group) and between October 2002 and April 2003 (NIDCAP group). Infants with congenital abnormalities or with

congenital infections were excluded, as well as infants with parents who were not able to communicate in either Dutch or English.

The conventional group received the standard care practiced in the NICU at that time. This included primary care nursing, skin-to-skin holding, promoting breastfeeding, early use of clothing, use of sheepskins, hammocks, provision of pacifiers and stuffed animals or toys. Parents were motivated to take part in daily care procedures. The NIDCAP group received adjustment and individualizing of care and environment based on the results of the behavioural observation belonging to the NIDCAP.[7,8] This observation visualizes the way of communication used by the preterm born infant. The infant is observed by a NIDCAP certified person. A caretaking interaction like suctioning, diaper change or blood sampling is observed. Included are a 10 minutes pre-activity and 20 minutes post-activity observation period. The observed behaviour is subdivided into five subsystems: autonomic, motor, state, attention/interaction and self regulatory system. Following the observation a case report is written assessing the infants' current ability to organize and modulate the subsystems. Current goals and caregiving recommendations to diminish stress and to support the individual infants' competence and development are formulated. Parents, nurses and doctors were coached by the NIDCAP trained nurses to use these recommendations in care of the infant observed. The observations start within 3 days after birth and are repeated every 7- 10 days or when major changes occur, and NIDCAP care ended at discharge from the NICU.

Neonatal characteristics were collected on gender, GA, birth weight, small for gestational age (SGA, $<P_{10}$[12]), mode of delivery, Apgar score, the Neonatal Therapeutic Intervention Scoring System score (NTISS) on day 1[13], treatment with surfactant, treatment with post-natal steroids, presence of a patent ductus arteriosus (PDA), infections, cerebral ultrasound findings before day three of life and infections (sepsis, meningitis, pneumonia, and necrotizing enterocolitis). Infants were screened and classified for retinopathy of prematurity (ROP) and a hearing screening was performed with the Automated Auditory Brainstem Response method (AABR).[14,15]

Multiple outcome parameters were taken into consideration: respiratory support status, cerebral ultrasound findings, growth, and length of NICU stay.

Respiratory support was defined as the number of days with at least 1 hour of respiratory support. This support could be mechanical ventilation, continuous positive airway pressure (CPAP) or nasal prongs. CLD was diagnosed as the need for supplemental oxygen at 36 weeks post-menstrual age. Cerebral ultrasounds were performed on day 3, 7, and before discharge, and on indication. Findings were independently classified by a radiologist and a neonatologist. Cerebral ultrasound findings were classified based on the most abnormal finding, normal: no haemorrhage, no ischaemia and no ventricular dilatation. Moderately abnormal: grade 1 or 2 haemorrhage[2] and/or grade 1 ischaemia[16] and/or grade 1 ventricular dilatation[17]. Severely abnormal: grade 3 or 4 haemorrhage and/

or grade 2 or 3 ischaemia and/or grade 2 ventricular dilatation. Weight was measured weekly, and height and head circumference biweekly until discharge as well as at term age.

The study was approved by the Research and Ethics Committee of our hospital.

Statistical Analysis

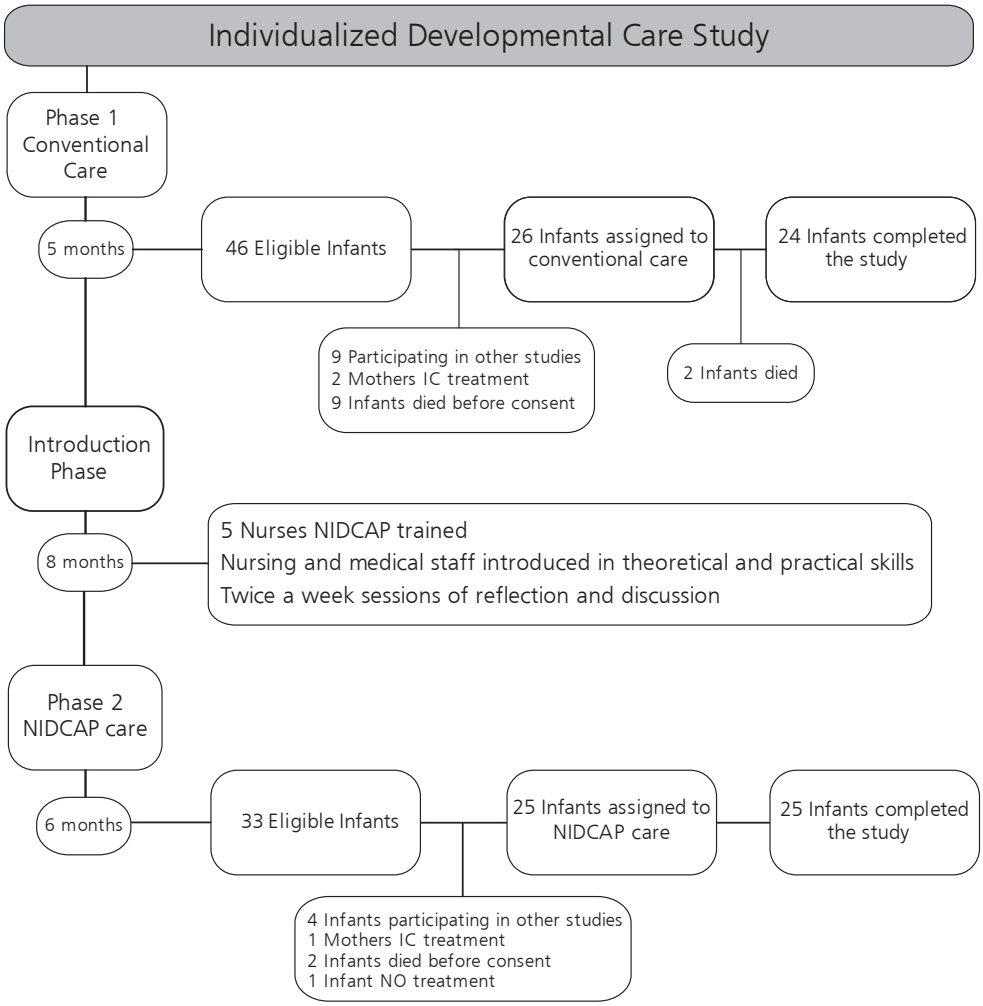
Results for continuous variables are expressed as means, standard deviations (SDs) and ranges for normally distributed variables and as medians and ranges in case of non–normal distributions. Chi-square statistics (Fisher's exact test when appropriate) and the Student's t-test or the Mann Whitney U-test, when appropriate, was applied for group comparisons.[18] Subsequently stepwise multivariate linear regression analysis was employed to adjust the effect of type of care on, respiratory support, growth, and length of NICU stay outcomes for differences in neonatal background characteristics. These characteristics were entered next to the type of care in a second step with a forward selection strategy, using the F-statistics with p=0.05 on the criterion level for inclusion. In case of a skewed distribution of the outcome measure, a natural log transformation was applied. To search for violations of necessary assumptions in multivariate regression analysis, normal plots of the residuals were produced as well as plots of the residuals versus predicted values by the model. Multivariate ordinal logistic regression analysis, using the proportional odds model, was used for the three level outcome cranial ultrasound findings. As numbers were small, only neonatal background characteristics that differed significantly between both care groups and that were univariately significantly associated with cerebral damage were introduced as an independent variable next to the type of care. The odds ratio (OR) can be interpreted as an estimation of the relative risk of having more severe cerebral damage (severe vs. moderate, moderate vs. no damage). All statistical analyses were performed using SPSS 12.0 software (SPSS, Chicago, IL, USA).

RESULTS

Fifty-one infants (26 conventional group and 25 NIDCAP group infants) were included in the study. Twenty-seven infants who met the study criteria were not included for various reasons. Flow of patients is visualized in Figure I.

The NIDCAP and conventional care groups differed with respect to some background neonatal characteristics (Table I). NIDCAP infants had a significantly lower birth weight (mean [SD] 1043 [191] g vs. 1154 [174] g, p = 0.044), were more often SGA (8 vs. 2, p = 0.038) and had a significantly smaller head circumference compared to the conventional care group (mean [SD] 25.1 [1.8] cm vs. 26.1 [1.3] cm, p = 0.041). In the conventional care group, significant more multiples were included (14 vs. 6, p = 0.029). During admittance

Figure I Individualized Developmental Care Study



at the NICU, significantly more infants in the NIDCAP group developed pneumonia (9 vs. 3, p = 0.040), which could be attributed to an outbreak of a nosocomial infection (i.c. *Klebsiella oxytoca*) in the entire NICU (i.e. also involved neonates not cared for by NIDCAP).

Two conventional care group infants died in the third week of life after treatment withdrawal based on poor neurologic condition. Except for cranial ultrasound findings, these infants could not be evaluated for outcome measures studied. None of the infants in the NIDCAP group died.

At inclusion none of the NIDCAP infants presented with cerebral haemorrhage as compared to four neonates of the conventional group (p = 0.110). During NICU stay one out of 25 NIDCAP infants (4.0%) newly developed severe cerebral damage, whereas in

Table I Neonatal Background Characteristics

	Conventional group	NIDCAP group	p
All subjects at inclusion	N=26	N=25	
Birth weight (g)	1154 (760-1465, 174)	1043 (615-1325, 191)	0.044
Gestational age (wk)	28.3 (26-29.9, 1.2)	28.3 (25.6-29.9, 1.2)	0.644
SGA (<P10)	2	8	0.038
Caesarean section	6	11	0.113
Apgar Score			
5 min (median, range)	8 (5-10)	9 (3-10)	0.117
Sex (male)	15	9	0.121
Multiples	14	6	0.029
Length (cm)	36.8 (27.0-41.5, 3.2)	35.8 (30.0-39.0, 2.4)	0.121
Head circumference (cm)	26.1 (21.8-28.0, 1.3)	25.1 (21.5-29.7, 1.8)	0.041
Antenatal Steroids	19	16	0.489
NTISS			
(1st 24 hours of life)	25.5 (11 – 32, 4.8)	24.6 (17 – 37, 5.1)	0.171
Cerebral Haemorrhage*			0.110
Haemorrhage gr 1	2	0	
Haemorrhage gr 2	2	0	
Mortality	2	0	0.161
Neonatal survivors	N=24	N=25	
Surfactant	17	14	0.493
Postnatal Steroids	5	3	0.703
PDA	11	12	0.683
Sepsis and/or Meningitis	8	9†	0.692
Pneumonia	3	9	0.040
NEC||	1	3	0.350
ROP (≥ stage 3)	1	0	0.490
AABR (refer)	3	1	0.349

Values are either mean (range, SD) or number of patients, statistical analysis was performed using Chi-square statistics (or Fisher's exact test) and Student's t-test (or Mann Whitney U-test), see statistical analysis

* Before day 3 of life

† 2 infants ≥ 3 periods of sepsis

NTISS=Neonatal Therapeutic Intervention Scoring System; PDA=patent ductus arteriosus; NEC=necrotizing enterocolitis; ROP=retinopathy of prematurity; AABR=automated auditory brainstem response

the conventional group nine out of 26 infants (35%) had severe cerebral damage (rate difference: -31%, 95% CI: -50 to -9%, p = 0.011) (Table II). Only in one of them cerebral haemorrhage was already present at inclusion (grade 2) which deteriorated into a grade 3 bleeding during NICU stay. The other eight cases developed severe cerebral damage after inclusion. Subsequent multivariate ordinal logistic regression also showed a significant decreased risk for cerebral damage in favour of NIDCAP (OR: 0.12, 95% CI: 0.03 to 0.46, p = 0.002). Confining the analysis to neonates without cerebral damage at inclusion yielded more or less similar results (OR: 0.2, 95% CI: 0.04 to 0.65, p = 0.01). Out of the neonatal background characteristics that differed significantly between both type of care groups, birth weight was the only covariate that was significantly associated with cranial ultrasound findings next to type of care.

Surviving NIDCAP infants had significantly more days of respiratory support as compared to infants in the conventional care group: median (range): 53 (0-406) days versus 22 (2-134) days (p = 0.021) (Table II). This difference could be partly attributed to one NIDCAP child with severe CLD who had 406 days of respiratory support as well as to the differences in background neonatal characteristics (birth weight, SGA, head circumference, multiples and pneumonia, see above). Taking these aspects into account in multivariate analysis, no difference in days of respiratory support was seen between

Table II Clinical Outcome of Surviving Infants

	Conventional group N=24	NIDCAP group N=25	p
Days on respiratory support	22 (2-134)	53 (0-406)	0.021
Days on ventilator	3.5 (0-26)	3.0 (0-36)	0.738
Days on CPAP	11 (1-43)	24 (0-45)	0.082
CLD	6	11	0.162
Cranial ultrasound findings*			0.019
Normal	11	17	
Moderately abnormal	6	7	
Severely abnormal	9†	1	
Weekly weight gain (g) ‡	72 (-93-141) (N=23)	81 (-23-208) (N=22)	0.183
Weekly length growth (cm) ‡	0.8 (0.0-2.7) (N=20)	0.6 (0.1-1.1) (N=21)	0.820
Weekly head growth (cm) ‡	0.6 (0.0-0.9) (N=22)	0.7 (0.0-1.0) (N=22)	0.291
Days in NICU	35 (9-99) (N=24)	46 (13-123) (N=25)	0.131

Values are either number of patients or median and range, statistical analysis was performed using Chi-square statistics (or Fisher's exact test) and Mann Whitney U-test, see statistical analysis
* deceased infants included
† 2 infants treatment withdrawn
‡ Only patients with data at birth and NICU discharge were analyzed
CLD=chronic lung disease

both care groups (mean [95% CI] difference NIDCAP vs. conventional: - 2.5 [-19.5 to 14.5] days, p = 0.766). The respective median (range) values for days on CPAP were 24.0 (0-45) days versus 11.0 (1-43) days (p = 0.072). After adjustment for the significant differences in neonatal background characteristics again, no difference in days on CPAP between both groups was observed (mean [95% CI] difference NIDCAP vs. conventional: 1.1 [-6.1 to 8.3] days, p = 0.753). Restricting the analysis to days on mechanical ventilation only, also no difference was observed between the NIDCAP and conventional care groups (NIDCAP vs. conventional, median [range]: 3.0 [0 to 36] days vs. 3.5 [0 to 26] days) both on a univariate and multivariate level.

In Table II growth during the NICU period is displayed for all infants with data at birth and discharge. Weekly weight gain, head and length growth were not statistically significantly different between NIDCAP and conventional care infants, both on a univariate and multivariate level after adjustment for the significant differences in previous mentioned background neonatal characteristics.

In the NIDCAP group median length of NICU stay was 46 days (range 13-123) as compared to 35 days (range 9-99) in the conventional care group (p = 0.131) (Table II). Also after adjustment in multivariate analysis for significant differences in previous mentioned neonatal background characteristics, no significant difference in NICU days was observed (mean [95% CI] difference NIDCAP vs. conventional: -2.0 [-15 to 11] days [p=0.795]).

Of the neonatal background characteristics that differed significantly between both type of care groups, a lower birth weight and pneumonia were significantly related to more days of respiratory support outcomes and more days of NICU stay. None of these neonatal background characteristics was significantly associated with growth variables (data not shown).

DISCUSSION

In this study, we compared the effect of individualized developmental care (NIDCAP) and conventional care on short term clinical outcomes of preterm neonates admitted to a tertiary NICU. Interestingly, NIDCAP infants had a lower incidence of cerebral damage during the NICU period as compared to infants in the conventional care group. This effect could neither be explained by differences between both groups in presence of cerebral haemorrhage at inclusion nor by other differences in neonatal background characteristics, nor by a secular trend of lower cerebral damage incidence in our NICU. The fact that NIDCAP is aimed at a reduction of stress and a better match between environment and brain development might be an explanation. As study numbers were small, this result needs to be interpreted cautiously and needs to be confirmed by further larger studies. Former studies only assessed incidence of intraventricular haemorrhage

(IVH) and not ischaemia and ventricular dilation. Evidence from these studies regarding IVH is conflicting, both a beneficial effect and no effect on incidence of IVH have been reported for NIDCAP as compared to conventional care.[19,20]

No significant differences were observed between NIDCAP and conventionally cared infants in terms of respiratory support, growth and length of NICU stay. With respect to respiratory support, results from previous studies are not consistent: two trials found a beneficial effect of NIDCAP[20,21] on days of mechanical ventilation while another trial[22] could not demonstrate an effect which is in accordance with our findings. The same applies for days on CPAP: one study found a favourable effect of NIDCAP whereas another study, in agreement with our study, did not observe a difference in days on CPAP between both type of care groups.[22,23] This discrepancy may be explained by differences in study populations as well as by the fact that comparison of respiratory outcomes between studies is complicated because they are flexible decisions.[24]

Also in accordance with our results previous studies reported no differences in growth during NICU stay.[21,22] In a previous three centre randomized controlled trial NIDCAP resulted in fewer ICU days; however, we could not confirm this beneficial effect in our study.[20] A possible explanation may be the fact that our conventional care contained already more developmental care aspects than the control care in the three-centre trial and the fact that our infants were initially relatively 'less sick'. Namely, in the three-centre trial only infants weighing < 1250 g and aged < 28 weeks, with a need for mechanical ventilation during at least 24 h within the first 48 h after birth were included, whereas in our study preterm infants born before < 30 weeks of GA were included without further restrictions regarding birth weight or need of ventilatory assistance. This is also supported by the fact that the beneficial effect of NIDCAP on ICU days in the three-centre trial was most outspoken in the centre with the initially sickest and socio-culturally most challenged families.[20] Additionally, comparison with other studies is difficult since in the Netherlands infants are transferred to referral hospitals as soon as intensive care is no longer required and consequently NIDCAP care ends. In previous studies from other countries infants stayed in the NICU and received NIDCAP care until discharge for home or at least until 36 weeks post-conceptional age.[19,20,22,25,26]

Some limitations of the present study need mentioning. Firstly, the present study concerned a non-randomized comparison. In our opinion a randomized design was not applicable because NIDCAP entails modification of nursing care that causes irreversible changes to caregivers' behaviour and environmental modifications and therefore may lead to contamination of the control care. Unfortunately, a cluster randomized controlled trial in many NICU's nationwide, was not an alternative option, because implementation of NIDCAP is expensive, labour intensive, and time consuming (training NIDCAP observers, modification of NICU environment, and caregiving activities). For this reason, many NICU's were not able or willing to invest this amount of money. Therefore, we chose a prospective phase-lag study design. Differences in background neonatal characteristics were accounted for in multivariate analysis. However, control for unknown confounders

is not possible with multivariate analysis and therefore may have influenced the study outcomes. Also the number of variables that could be accounted for was limited due to the relatively small sample size. Furthermore, a phase-lag design carries the risk of possible changes in medical and nursing care over time that may influence the outcomes. But we are not aware of important changes in medical and nursing care during our study period. On the other hand, a phase-lag design has the advantage over a parallel group design that potential spill over of developmental care aspects to the control group is avoided. Inherent to the complex nature of NIDCAP, it is extremely difficult to achieve a standard experimental design in this kind of study, as has been acknowledged by others.[24] Recently qualitative research and continuous quality assessment benchmarking have been advocated to help evaluate the benefits of developmental care and offer a better understanding of the impact of this care.[27]

Keeping in mind these limitations, we conclude with precaution that in our study NIDCAP may have resulted in less severe cerebral damage. This result needs confirmation by further studies in large patient numbers. We recently reported that parents of infants cared for by NIDCAP were significantly more satisfied with this type of care than parents of infants cared for by conventional care.[28] In light of our findings, and in line with others[24], we conclude that NIDCAP deserves further exploration, including cost-effectiveness analysis.

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Chapter 6

Development and growth in very preterm infants in relation to NIDCAP in a Dutch NICU: two years of follow up

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Submitted

ABSTRACT

Aim To study development and growth in relation to Newborn Individualized Developmental and Assessment Program (NIDCAP®) for infants born with a gestational age of less than 30 weeks.

Methods Developmental outcome of surviving infants, 25 in the NIDCAP group and 24 in the conventional care group, in a prospective phase-lag cohort study performed in a Dutch level III neonatal intensive care unit (NICU) was compared. Main outcome measure was the Bayley Scales of Infant Development-II (BSID-II]) at 24 months corrected age. Secondary outcomes were neurobehavioral and developmental outcome and growth at term, 6, 12 months and 24 months.

Results After adjustment for group differences and known outcome predictors no differences were seen between both care groups in BSID-II at 24 months. At term age NIDCAP infants scored statistically significant lower on neurobehavioral competence; motor system (median [IQR] 4.8 [2.9-5.0] vs. 5.2 [4.3-5.7], p = 0.021) and autonomic stability (median [IQR] 5.7 [4.8-6.7] vs. 7.0 [6.0-7.7], p = 0.001). No differences were seen in other developmental outcomes. After adjustment for background differences, growth parameters were comparable between groups during the first 24 months of life.

Conclusion At present the strength of the conclusions to be drawn about the effect of NIDCAP on developmental outcome or growth at 24 months of age is restricted. Further studies employing standardised assessment approaches including choice of measurement instruments and time points are needed.

INTRODUCTION

Preterm infants are at risk of poor developmental outcome due to both their immature and inadequate organizational system and being early in the hostile extra uterine environment.[1-5] The environment of the Neonatal Intensive Care Unit (NICU), with its constant noise, light, and activity is completely different from the intrauterine environment and challenges the preterm infant during a phase of rapidly evolving and vulnerable brain development. In general preterm infants discharged from the NICU's show more developmental delay compared to their full term peers.[6-8] More than 50% of these preterm infants appear to have minor deficits such as visual-motor integration problems, motor impairment, attention disorders, hyperactivity, speech and language delay, behavioural problems and learning disabilities.[6-10] Severe developmental problems are encountered in only a minority of preterm infants.[6-10]

In an effort to improve developmental outcome, attention has shifted towards neuroprotective strategies and early neurodevelopmental support. Against this background the Newborn Individualized Developmental Care and Assessment Program (NIDCAP) has been designed in order to create a NICU environment that minimizes stress experienced by the infant. NIDCAP involves sequential, formalized, naturalistic observations of the infant prior to, during and after caregiving procedures.[11,12] Moreover, the infants' behaviour enables the observer to assess the infants' efforts to cope with the environmental stimuli and to facilitate his development.

Previous systematic reviews of randomized controlled trials and cohort studies[13-15] found limited evidence for the benefit of NIDCAP on neurodevelopment up to 24 months corrected age. No major adverse events have been reported. The aim of the present study was to examine growth and neurodevelopmental outcome up to 24 months corrected age in preterm born infants after NIDCAP as compared to conventional care in a Dutch NICU. Recently we reported on their short-term medical outcomes.[16]

METHODS

A prospective phase-lag cohort study in a level III NICU of the Emma Children's Hospital / Academic Medical Center in Amsterdam, the Netherlands was performed. The first phase (control phase) concerned a prospective cohort study of neonates receiving conventional care (August 2001 until January 2002). This phase was followed by a NIDCAP introduction phase during which five nurses were NIDCAP trained and certified as NIDCAP observers. All other NICU nursing and medical staff was introduced in theoretical principles and practical skills necessary to be able to apply the intervention.[16] After this introduction phase a second cohort of neonates receiving NIDCAP was studied (October 2002 until April 2003).

Infants born before 30 weeks of gestational age were consecutively included after parental informed consent. Infants with congenital abnormalities or with congenital infections were excluded as well as infants with parents who were not able to communicate in either Dutch or English. The study was approved by the Research and Ethics Committee of our hospital. All children alive at NICU discharge were followed for development and growth up to 24 months corrected age (Figure 1). The design of the study as well as the short-term medical findings have been described in more detail elsewhere.[16]

Conventional and NIDCAP Care

The conventional care group received the standard care practiced at the NICU at that time. This included primary care nursing, overall encouragement of skin-to-skin holding (kangaroo care), promotion of breastfeeding, early use of clothing in the incubator, use of sheepskins, hammocks, provision of pacifiers and stuffed animals or toys. Keeping a diary was also common habit. Parents were motivated to take part, as much as possible, in daily care procedures. NIDCAP group infants received adjustment and individualizing of care and environment based on the results of the Naturalistic Observation of Newborn Behavior (NONB), a behavioural observation method in NIDCAP.[11,12] The infant was observed before, during and after a caregiving activity, like suctioning, diaper change, feeding session or blood sampling by a NIDCAP certified nurse. The observer had no interaction with the infant. The observed behaviour was subdivided into five subsystems; autonomic, motor, state, attention/interaction and self regulatory system. In the case report following the observation the infants' current ability to organize and modulate the five subsystems was assessed and described. Moreover, current goals of the infant and care giving recommendations to support the individual infants' development were given. Each observation started within three days after birth and was repeated every seven to ten days or when major changes occurred. The NIDCAP intervention lasted as long as the infant stayed in the NICU.

Developmental outcome

Main developmental outcome was the Bayley Scales of Infant Development-II (BSID-II) [17, 18] at 24 months of corrected age. Furthermore, BSID-II at 6 and 12 months of corrected age was applied as secondary outcome as well as the Neonatal Behavioral Assessment Scale (NBAS)[19] at term age, and the Touwen examination[20] at 6, 12 and 24 months.

All assessments were performed during routine follow up visits at the out patient clinic and were performed by the same experienced assessors (child physical therapist [NBAS], neonatologist [Touwen] and child psychologist [BSID-II examination]).

Bayley Scales of Infant Development-II (BSID-II)

The BSID-II includes a Mental Developmental Index (MDI) and Psychomotor Developmental Index (PDI). These indices have been standardized to a mean of 100 and a standard

deviation of ± 15. Subnormal (mildly delayed) and abnormal (significantly delayed) development are defined as being present when the total score is <85 (- 1 SD) or <70 (- 2 SD), respectively.[18]

Infants received the lowest possible score if either PDI or MDI assessment was disrupted due to the infant's behaviour and if more than four items were omitted as a result. Since Dutch or European norms were lacking at the time of assessment the American norms were used for scoring.[18]

Neonatal Behavioral Assessment Scale (NBAS)

The NBAS evaluates the infants' autonomic stability, motor organization, state organization and attention/interactive capacities with a seven cluster scoring method. Each cluster is scored on a nine-point scale (possible range 1-9 points), where a higher score represents a more optimal performance.[19] The cluster on reflexes consists of 18 different reflexes and the score reflects the total number of abnormal reflexes (possible score range 0-18 points).

The scoring of the NBAS includes seven supplementary items but the "Emotional Response of the Examiner" item was omitted in this study. The supplementary items are constructed to measure the quality of the infant's performance and capture the more subtle signs of stress that may not be detected by the standard scale items. Each supplementary item is scored on a nine-point scale (possible score range 1-9 points), a higher score represents a more optimal performance.[19]

Touwen examination

The Touwen neurological examination addresses five neurological domains: tone and posture, muscle power, reflexes, co-ordination and balance, and involuntary movements. Neurological findings are classified as normal, mild abnormal or abnormal neurological function.[20] Abnormal development was defined as severe abnormality of tone, posture and movement leading to a functional impairment and /or delay in motor development. A mild abnormal development was defined as a moderate abnormality of tone, posture and movement leading to a minor functional impairment or a minor developmental delay.

Growth outcomes

Weight, height, and head circumferences were measured at term age and at 6, 12, and 24 months of corrected age.

Statistical Analysis

Because of rapid changes in infant development at young ages, BSID-II scores of young infants (0-18 mo) show low test-retest reliability and high intrasubject variability. As a result, changes in our subjects' performance due to the intervention cannot easily be discerned at these young ages.[17,21] Therefore, primary analyses are focused on the BSID-II outcomes at 24 months of corrected age. Moreover, BSID scores are generally considered the gold standard for psychomotor development and are the most frequently used

measures of developmental outcome. For the other outcomes and time points descriptive analyses are performed.

Continuous variables are expressed as means, standard deviations (SDs) and ranges in case of normally distributed variables and as medians and their interquartile ranges (IQRs) in case of a non-normal distribution Chi-square statistics (Fisher's exact test when appropriate) and the Student's *t*-test or the Mann Whitney U-test, when appropriate, were applied for group comparisons. Multivariate linear regression analysis (with stepwise forward selection strategy) was employed to study the effect of type of care on BSID-II scores at 24 months of age adjusted for well-known confounders (i.e. birth weight, gender, surfactant, postnatal steroids, sepsis/meningitis, cranial ultrasound findings, maternal age, ethnic origin and occupational status). These variables were entered next to the type of care in a second step with forward selection strategy, using F-statistics with p=0.05 on the criterion level for inclusion. To examine differences in growth outcomes over time between both type of care groups we used linear mixed model analysis with the restricted maximum likelihood estimation method. The mixed procedure allows analysis of all available information of all patients, thus including patients with incomplete data.

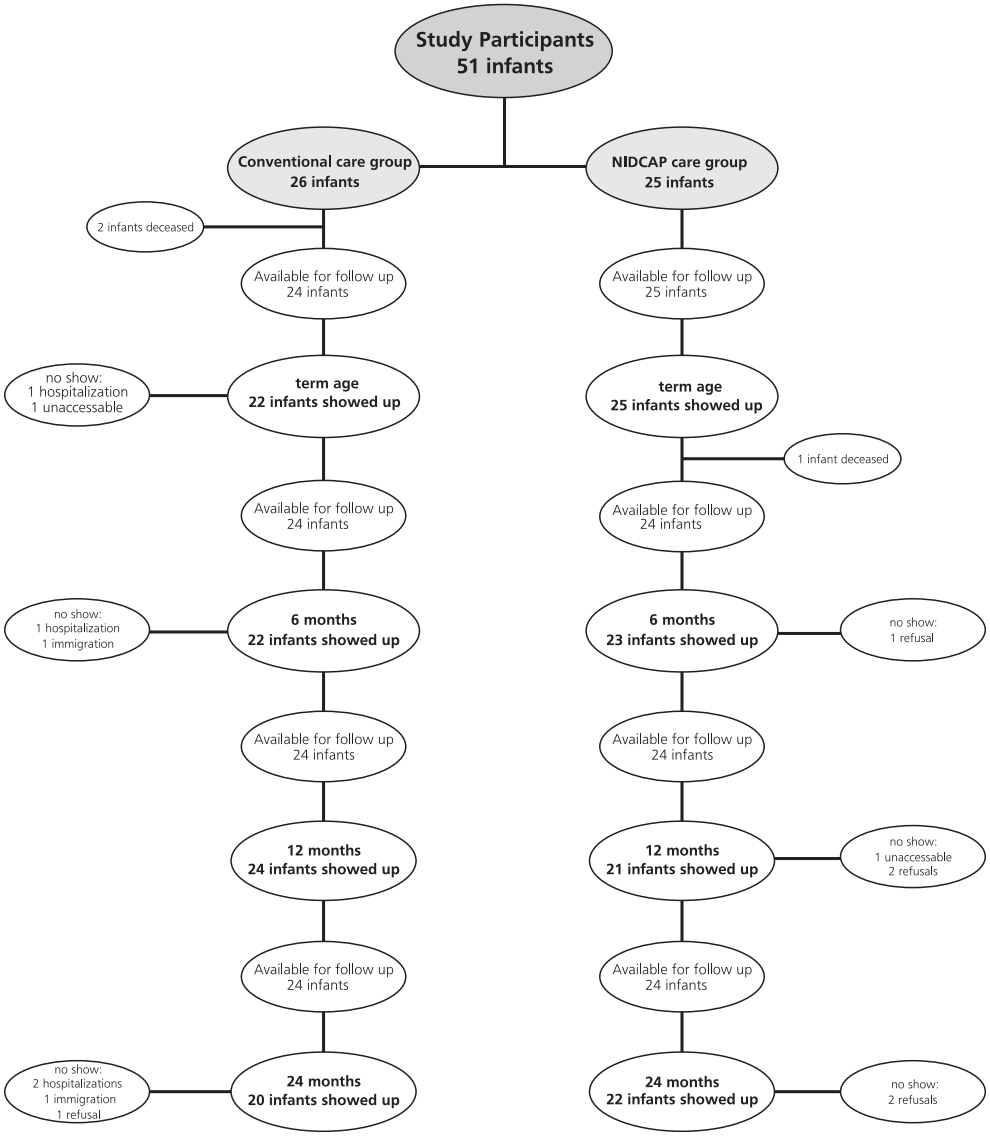
All statistical analyses were performed with SPSS 12.0 software (SPSS, Chicago, IL, USA).

RESULTS

At 24 months corrected age, 24 out of 26 infants in the conventional care group and 24 out of 25 infants in the NIDCAP care group were still alive (Figure 1). Two infants of the conventional care group died within 14 days of life, treatment was withdrawn because of their poor neurological condition. The proportion NICU stay, i.e. the length of being exposed to NIDCAP care in relation to the total length of hospital stay amounted to 57.3% (range 22.0% - 100%, SD 25.1%) as compared to a proportion of NICU stay of 51.2% (range 16.0% - 100%, SD 24.1%) in the conventional group, did not differ statistically significantly (p = 0.363). One infant in the NIDCAP group died of sepsis at seven weeks post term. This infant was included in analyses at term age only. Not all infants showed up at all follow up assessments in the outpatient clinic (Figure I).

At inclusion the NIDCAP and conventional group were similar with respect to social economical status but differed with respect to some neonatal characteristics (Table 1): NIDCAP infants had a significantly lower birth weight, were more often small for gestational age, had a smaller head circumference and were less often multiples compared to the conventional care group. None of the NIDCAP infants presented with cerebral haemorrhage at inclusion as compared to four neonates of the conventional group (grade 1 or 2 haemorrhage). During NICU stay less severe cranial ultrasound findings were seen in the NIDCAP group, also after adjustment for the observed differences in

Figure 1 Follow Up Profile of the Study Participants



background characteristics. The respiratory support period was significantly shorter for the conventional care group; however this difference disappeared after adjustment for differences in background characteristics. These findings have been elaborated in our earlier report on short-term medical outcomes.[16]

Table 1 Characteristics of surviving infants and their parents

	Conventional group (N=24)	NIDCAP group (N=25)	p
Baseline			
Gestational age (wk)	28.5 (26.0-29.9, 1.1)	28.3 (25.6-29.9, 1.2)	.452
Birth Weight (g)	1162 (760-1465, 174)	1043 (615-1325, 191)	.032
Length at birth (cm)	36.9 (27.0-41.5, 3.3)	5.8 (30.0-39.0, 2.4)	.093
Head circumference at birth (cm)	26.0 (21.8-28.0, 1.6)	25.3 (21.5-29.7, 1.8)	.025
SGA (<P10)	2	8	.042
Apgar Score (5 min)	8 (5-10)	9 (3-10)	.137
Gender (male)	14	9	.121
Multiples	14	6	.016
Sectio Caesarea	6	11	.167
Antenatal Steroids	18	16	.414
NTISS			
(score of 1st 24 hours of life)	25.3 (11 – 31, 4.8)	24.6 (17 – 37, 5.1)	.210
Cerebral Haemorrhage			
(gr 1,2/gr 3,4) *	4/ 0	0/0	.035
During Hospitalization			
Respiratory support†	22 (2-134)	53 (0-406)	.021
Days on Ventilator	3.5 (0-26)	3.0 (0-36)	.738
Surfactant	15	14	.647
Postnatal Steroids	5	3	.408
NEC	1	3	.322
PDA	9	12	.462
Sepsis and/or Meningitis	8	9‡	.846
CLD¶	6	11	.167
Cranial ultrasound findings	11-6-2007	17-7-2001	.048
normal-moderately abnormal-			
severely abnormal§			
ROP (≥ stage 3)	1	0	.307
ABBR (refer)	3	1	.282
Days on NICU	38 (9-99)	49 (13-123)	.131
Social Economical Status			
Mean maternal age (yr)	30.4 (21-39, 4.5)	31.8 (16-40, 5.6)	.221
Maternal ethnic origin: Western	20	19	.529
Maternal Education Level‖			
Low-Middle-High	3-16-5	3-13-9	.349
Mother working	18	17	.592
Family status of two parents	24	21	.043

Legend to Table 1 Characteristics of surviving infants and their parents

Values are either number of patients, mean (range, SD) or median (range)
*Before day 3 of life
† Respiratory support = total days ventilator, continuous positive airway pressure or nasal prongs
‡2 infants ≥ 3 periods of sepsis
§ normal: no haemorrhage and no ischemia and no ventricular dilatation; moderately abnormal: a grade 1 or 2 haemorrhage and/or a grade 1 ischemia and/or a grade 1 ventricular dilatation; severely abnormal: a grade 3 or 4 haemorrhage and/or a grade 2 or 3 ischemia and/or a grade 2 ventricular dilatation
|| Education level: Low < high school, Middle = high school, High > high school
NEC = necrotizing enterocolitis, PDA = patent ductus arteriosus, CLD = chronic lung disease, ROP = retinopathy of prematurity, ABBR = automated auditory brainstem response

BSID-II

No differences in MDI or PDI scores were seen between the NIDCAP and conventional care groups at 24 months of corrected age, neither at 6 or 12 months, both for mean scores as well as for proportions classified as (sub)normal and abnormal (Table 2). In both care groups the greater majority had (sub)normal BSID-II scores up to 24 months of corrected age.

Also after adjustment for well-known predictors of developmental outcome (see methods section), no differences were observed in PDI or MDI at 24 months corrected age between both care groups.

NBAS and Touwen

At term age, the infants' neurobehavioral competence differed between both care groups on the NBAS. Infants in the NIDCAP group scored significantly lower than the conventional group regarding the clusters motor system (median [IQR]: 4.8 [2.9-5.0] vs. 5.2 [4.3-5.7], p = 0.021) and autonomic stability (median [IQR]: 5.7 [4.8-6.7] vs. 7.0 [6.0-7.7], p = 0.001) (Table 3). The habituation cluster was omitted because the optimal state for the administration of the habituation cluster is a sleep state and most of our infants were in a drowsy or awake state. On three of the six supplementary items the NIDCAP group scored significantly lower: quality of alertness (median [IQR]: 4.0 [3.0-5.0] vs. 5.0 [4.0-6.5], p = 0.025), cost of attention (median [IQR]: 5.0 [5.0-5.0] vs. 6.0 [5.0-7.0], p = 0.004), and state regulation (median [IQR]: 5.0 [4.0-6.0] vs. 7.0 [5.0-8.0], p = 0.018) (Table 3).

Neurodevelopment according to Touwen was classified as normal in the majority of infants in both the NIDCAP and conventional care group at 6, 12 and 24 months of age (Table 2).

Growth

A significant increase with time for all growth parameters was seen. After correction for their respective baseline values, no significant differences in the course over time of weight, height and head circumference were observed between both type of care groups.

Table 2 Developmental outcome at different ages corrected for prematurity

	6 months		
	CV (N=22)	NIDCAP (N=23)	p
Touwen			
normal (n)	16	20	
mild abnormal (n)	4	3	.175
abnormal (n)	2	0	
BSID-II*			
Psychomotor Developmental Index †	81.8 (17.6)	74.6 (14.1)	.094
(sub)normal (n)	18	15	.446
abnormal (n)	4	8	
Mental Developmental Index†	88.6 (11.8)	90.9 (8.4)	.393
(sub)normal (n)	21	22	.627
abnormal (n)	1	1	

*Bayley Scales of Infant Development-II
† value represent mean (SD)

Table 3 Neurobehavioural Outcome at term age

	Conventional group (N=21)	**NIDCAP group** (N=25)	**p**
NBAS	median (IQR)	median (IQR)	
Cluster scores			
Orientation*	4.1 (3.6- 5.4)	3.9 (2.3- 4.9)	.229
Motor system*	5.2 (4.3- 5.7)	4.8 (2.9- 5.0)	.021
Range of state*	4.0 (2.9- 4.1)	4.0 (3.4- 4.3)	.376
Regulation of state*	4.8 (3.5- 5.3)	4.8 (3.9- 5.9)	.364
Autonomic stability*	7.0 (6.0- 7.7)	5.7 (4.8- 6.7)	.001
Reflex score†	2.0 (1.0- 3.0)	3.0 (1.0- 5.0)	.068
Supplementary items*			
Quality of alertness	5.0 (4.0- 6.5)	4.0 (3.0- 5.0)	.025
Cost of attention	6.0 (5.0- 7.0)	5.0 (5.0- 5.0)	.004
Examiner's facilitation	5.0 (4.0- 6.0)	5.0 (4.0- 6.0)	.435
General irritability	5.0 (5.0- 5.5)	5.0 (4.5- 6.0)	.510
State regulation	7.0 (5.0; 8.0)	5.0 (4.0- 6.0)	.018
Robustness/endurance	5.0 (4.0- 6.5)	4.0 (3.0- 5.5)	.063

IQR, interquartile range
* possible scoring range 1-9
† possible scoring range 0-18

12 months			24 months		
CV (N=24)	NIDCAP (N=21)	p	CV (N=20)	NIDCAP (N=22)	p
18	18		17	22	
5	1	.232	1	0	0.90
1	1		2	0	
79.2 (15.6)	79.7 (12.5)	.982	74.5 (13.1)	80.7 (15.3)	.117
18	17	.577	12	17	.142
6	4		8	5	
82.8 (12.6)	87.0 (10.7)	.299	90.1 (16.6)	86.1 (14.7)	.267
21	21	.872	18	19	.653
3	3		2	3	

DISCUSSION

In this study in very preterm infants, we did not observe a significant difference between NIDCAP and conventional care in mental or psychomotor developmental outcome at the corrected age of 24 months compared to conventional care as measured with the Bayley Scales of Infant Development-II. At term age NIDCAP group infants were still autonomic and motor (NBAS) less stable compared to conventional care infants. No differences were seen in the neurological status (Touwen) or growth parameters during the first 24 months of age.

The long-term developmental effect of the NIDCAP intervention has been evaluated and summarized by others.[13,14,22-26] However different times of measurement and different versions of the BSID scales were used.[22-26] Only one study assessed developmental outcome at 24 months and used BSID-II[26] as we did. No differences were seen in mental and psychomotor development as in our study.

Two previous meta-analyses of studies on developmental outcome up to 9 to 12 months did not show a significant benefit of NIDCAP compared to conventional care.[13,14] Results of individual studies included in this meta-analyses however, were conflicting; two studies reported a beneficial effect of NIDCAP on both mental and psychomotor development and one study reported benefit on mental development only.[23-25] Yet, another study could not detect a favourable effect of the NIDCAP on both mental and psychomotor development up to 12 months.[26]

Interestingly, similar developmental outcome of NIDCAP infants at 24 months of age as compared to conventional care infants was observed despite their more fragile condition as reflected in their lower NBAS scores at term age. Post hoc analysis was performed to correct for this difference in autonomic and motor stability, however this did not change the results. If an infant's autonomic stability is weak as the respective NBAS score of the NIDCAP group suggests (median (IQR) 5.7 (4.8-6.7), possible score range 1 to 9, this will also be expressed in lower scores in other NBAS clusters, since a certain level of autonomic stability is requested to perform well in the other clusters. The differences in NBAS scores could not be attributed to well known confounders, since these differences persisted after adjustment for these confounders in post hoc analyses. Also the fact that in the NIDCAP group three infants were still admitted to the NICU at the time of the NBAS assessment as compared to one infant in the conventional group could not partly explain the observed differences since exclusion of these children from the analysis did not yield a different picture (data not shown).

We also found no differences in neurological outcome during the first 24 months of age between both care groups as measured with the Touwen test. There appeared, more infants in the conventional group with (mild) abnormal scores, however study numbers are too small to allow inferences. Since the Touwen test is not suited to detect minor or subtle neurological abnormalities, this may have left possible differences undetected. Comparison of our NBAS and Touwen results with others is not possible because other studies on the developmental outcome of NIDCAP did not include these instruments. Regarding growth outcomes information of previous NIDCAP studies is limited to 9 months follow up, no differences were reported.[22,27]

As we elaborated in more detail in our previous report[16], the present study suffered from a non-randomized comparison and the small number of infants, so the possibility of a type 2 statistical error cannot be excluded. On the other hand, a phase lag design has the advantage over a parallel group design that the risk of spill over to the control group is avoided. As we previously pointed out[16], NIDCAP is a complex intervention, so compared with drug trails. In addition the fact that neonates are discharged from the NICU to different referral hospitals which vary with respect to the amount of developmental care offered, compromises the evaluation. For this reason other methodological approaches, such as qualitative research and continuous quality assessment benchmarking may help to evaluate the benefits of developmental care.[28,29]

All together the above mentioned issues restricted the strength of conclusions that may be drawn at present about the effect of NIDCAP on developmental outcome or growth at 24 months of age. Therefore, there remains a need in this area for further well-designed studies in sufficient numbers. In order to enhance the generalisability and comparability of neurodevelopmental outcomes and to facilitate meta-analyses, a standardised assessment approach including choice of measurement instruments and time points is needed. Additionally further psychometric evaluation and adaptation of

instruments is necessary to improve their measurement properties. Future studies should also address cost-effectiveness of NIDCAP.

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Chapter 7

How satisfied are parents supported by nurses with the NIDCAP® model of care for their preterm infant?

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ABSTRACT

Main purpose of implementing the Newborn Individualized Developmental Care and Assessment Program (NIDCAP®) in our Neonatal Intensive Care Unit from perspective of quality of care was to bring about an improvement in the satisfaction of parents. This was measured by means of the NICU- Parent Satisfaction Form and the Nurse Parent Support Tool. Parents were significantly more satisfied with caregiving according to NIDCAP® principles than they were with the traditional care for their premature infants.

INTRODUCTION

The scope of customers' participation in the evaluation of healthcare service has broadened during the last decade. In particular, customers' satisfaction has become a widely accepted measure of quality of care. Satisfaction, defined as a personal evaluation of care services and care providers, is viewed as vital in the assessment of quality of care.[1]

A common problem with satisfaction rating instruments is that ratings are universally high. Many factors have been identified as contributing to the overall positive responses, including social desirability, implicit threat, hesitance to express negative opinions, and item wording.[2-7] Conceptual issues regarding patients' (parents') satisfaction were subject of research mainly in the 1980s – 1990s. Yet, the theoretical basis of patients' satisfaction with their hospital experience as well as patients' satisfaction with nursing care remained unclear. More recently research on patients' perceptions of nursing care showed four conceptual categories - seeing the individual patient, responding, explaining, and watching over - as major contributors to the level of satisfaction.[8]

Hall and Dorman's systematic review of 221 satisfaction studies reported on the mediating role that satisfaction may play between care provider behavior and changes in health status of patients.[9] They identified external factors that contribute significantly to patients' satisfaction, such as the experience of the caregiver and the type of care provided. Additional factors were the number of items and the specificity of the questionnaire, and whether or not the questionnaire was internally constructed.

In child health care the parents are asked, as legal guardians, to rate the quality of care.[10,11]

Mitchell-DiCenso et al pointed out that parental satisfaction is highly dependent on the amount and quality of communication between care providers and parents.[12] Parents convey a strong message to care providers about the importance of being kept informed about the care their infant is receiving and the infant's progress. Satisfaction identifies the match between the unit culture and the parents' expectations.[13]

Previous research has indicated that parents of infants hospitalized in a neonatal intensive care unit (NICU) are particularly stressed by the appearance and behavior of their sick infant and by the alterations in their parental role.[14-16]

Encouraging parents to spend more time with their infants and to actively participate in their care is believed to facilitate parental role development.[17] Knowledge of nurses' attitudes regarding parents and other family members' participation in care is limited, though the literature indicates that the nature and extent of parental participation is presently under nurses' control.[17]

Parental feedback, similar to parental satisfaction, provides data to compare changes in nursing care and allows monitoring of trends for improvement. However, only one study was found on the support of nurses to parents, while no studies were found

relating the increase of the parental involvement to a decrease of stress and/or parental satisfaction.[14]

Knowing how stressful the period in a NICU is and knowing parents are distressed by the loss of their expected parental caregiving role with their newborns, we hypothesized that implementing family-centered developmental care could make a difference. The Neonatal Individualized Developmental Care and Assessment Program (NIDCAP®) changing practice from profession-centered approach to an approach involving shared decision making and responsibility in caregiving, would contribute to improvement in parents' perceived support and satisfaction.

METHODS

The study was carried out in the level III NICU of the Emma Children's Hospital / Academic Medical Center in Amsterdam, The Netherlands. Parents of 50 infants born before 30 weeks of gestational age and living in the region of Amsterdam were included in the study. Excluded were parents of infants with chromosomal, syndromal or congenital abnormalities, as well as infants with congenital infections. Parents speaking insufficient Dutch or English were excluded as well. The Medical Ethics Committee approved the study.

The control group (25 infants) received traditional neonatal care practiced at that time. After collecting data of this group, the NIDCAP was introduced.[18] The intervention group received care according to general NIDCAP principles (Figure I). After written informed consent was obtained, formal observations of the infants' behavior were started within

Figure 1 Newborn Individualized Developmental Care and Assessment Program

NIDCAP® is an integrated developmental care intervention. The major instrument used in the NIDCAP is repeated, formalized observations of the infant by a specially trained and certified person. These observations focus on efforts at self-regulation, as revealed by approach or avoidance behavior. When the sensory input is appropriate, the infant will move toward the stimuli and demonstrate self-regulatory behavior. When the input is overwhelming or inappropriate in timing, the infant shows avoidance or stress behavior.

Caregiving plans, including recommendations concerning individualized care, and environmental changes are designed on the basis of the current developmental stage and medical condition of the infant, as well as on the needs of the family. As the infant matures, these recommendations are modified in an appropriate manner.

Caregivers learn to watch sensitively and note the reactions of the infant to different types of handling and care, and thus make continuously appropriate adjustments. NIDCAP is family centered; the goal is to empower the family as part of the healthcare team.

three days after birth. These observations where repeated every seven to ten days for as long as the infant remained in the unit. Recommendations resulting from the observations were discussed in detail with the professional in charge and the parents.

Data collection of the control group took place between August 2001 and April 2002, followed by data collection of the intervention group between October 2002 and July 2003.

Between these periods professionals were trained in the theoretical principles and practical skills of NIDCAP. The data concerning parents' satisfaction and perceived support from nurses were collected by means of the NICU- Parent Satisfaction Form (NICU-PSF) and the Nurse Parent Support Tool (NPST).[19,20] We also collected parental demographics about age, ethnic background, education level and socioeconomic status, and data about gestational age, birth weight, gender, and multiple births. Data concerning the severity of illness of the infant were collected by means of the Neonatal Therapeutic Intervention Score (NTISS)[21] and the infants' length of stay in the NICU.

Both questionnaires (NICU-PSF and NPST) were translated from English to Dutch by one of the nurses in collaboration with the nurse researcher (JW). Thereafter, a bilingual (English/Dutch) neonatal nurse teacher translated the questionnaires back into English. The latter was sent to the authors of both scales and approval was received.

The scale was tested with three parents on comprehensiveness and clarity of the items before the study.

Both questionnaires were given to parents on the day their infant was transferred to another hospital or was discharged home, together with a written request to send back the questionnaire as soon as possible in the envelope provided. The parents were asked for permission to contact them if the questionnaires were not received within the following three weeks.

Assessment tools

The NICU-PSF is a self-reporting questionnaire developed to measure parents' perceptions of care. It targets areas for improvement and evaluates the quality of care delivered, in meeting and exceeding the needs and expectations of parents and their families who receive neonatal care services. The NICU-PSF is a 62-item questionnaire with closed and open-ended questions. The concepts include general satisfaction, continuity of care, communication and information, preparedness, involvement in care, being a parent, being near the baby, support, and follow up. The final questions are about pleasures and disappointments and suggestions for improvement. Different rating scales were used, such as a 5-point rating scale ranging from "extremely satisfied" to "not at all satisfied" or "excellent" to "poor". Questions reporting frequencies ranged from "all the time" to "none of the time" and "prepared" to "not nearly prepared". There were also some questions with dichotomous and categorical responses. The number of (sub)questions per concept differed from 3 to 12.

Scores differed per concept due to the number of questions per concept from 3 to 57 points, because of the number of questions per concept. The scale has been tested for reliability and validity. Internal consistency (r_{ic}) is reasonably good for four categories (0.52-0.67) and good for five categories (> 0.70).[15] Content validity was established through literature review, parent open/ended interviews, parent panel, neonatal staff review, and pilot pretesting. Discriminant validity was tested by determing the correlations of the items and by comparing the correlations to other constructs; internally consistency was reached. Criterion validity was not achieved because of the lack of a gold standard instrument for comparison. [20]

The NPST is a self-reporting instrument 21 item. Parents are asked to rate the amount of nursing support they received from the nursing staff on a Likert-type scale as follows: 1 = almost never, 2 = not very often, 3 = some of the time, 4 = most of the time, and 5 = almost always. The scoring is done by summing the items that are rated, divided by the number of items completed. The range of scores is from 1 to 5 with higher scores reflecting greater amounts of perceived support from the nursing staff. The scale makes use of four dimensions - information, appraisal, emotional support, and nursing care - to measure the amount of support. (1) The information dimension includes informational support, supportive communication, and ongoing information related to the child's illness, treatments, care and related issues. (2) The appraisal dimension involves nurses' esteem support on respecting, enhancing, and supporting the parent role. (3) The emotional support dimension involves helping parents to cope with their responses and needs related to the child's illness. (4) The nursing care dimension incorporates the quality of care provided to the child. The psychometric properties have been tested. The internal consistency of the NPST is high, Cronbach's α being 0.95 (mothers: 0.94 and fathers: 0.96). Validity was supported by correlating the total scale score with the Stress Support Scale (r = 0.76).[19]

RESULTS

General

Characteristics of parents as well as their infant are summarized in Table I. In the control group, 2 infants died and their parents did not receive the questionnaires. The last infant to be included was one of a twin; therefore both were included, leading to 24 infant-parent dyads for analysis. In the intervention group, 25 dyads were analyzed. Some differences were seen between the groups. The infants of the intervention group had a significantly lower birth weight (Mann Whitney U-test = 193.00, p = 0.032). Significantly more twins were included in the control group (Fisher exact test value = 5.975, p = 0.015). No differences were seen between the mothers groups. Fathers in both groups differed in age and educational level, but the differences were not statistically significant.

Table I Characteristics of (surviving) study infants and their parents

	Control group N = 24	Intervention group N = 25
Gestational age, wk	28.5 (26.0-29.9)	28.3 (25.6-29.9)
Mean birth weight, g	1162 (760-1465)*	1043 (615-1325)*
Male/ female	14 / 10	9 / 16
Singleton / multiples	10 / 10†	19 / 6†
Parents married or attached	24	22
	N = 17	N = 22
Mean maternal age at delivery, y	30 (21-39)	32 (16-40)
Maternal ethnic origin		
Western / non Western	14 / 3	15 / 7
Maternal education level‡		
Low	2	3
Middle	11	12
High	4	7
Mother working		
Yes/no	12 / 5	13 / 9
	N = 17	N = 19
Mean father's age, y	33 (20-41)	38 (31-61)
Father's ethnic origin		
Western / non Western	13 / 4	17 / 2
Father's education level‡		
Low	0	4
Middle	10	6
High	7	9
Father working		
Yes/no	17 / 0	16 /3

* Mann Whitney U-test = 193, p = 0.032
† Fisher's exact test value = 5.975, p = 0.015
‡ Low = < high school
Middle = high school
High = > high school

No between-group differences were seen for the NTISS. Mean score on day 1 was 25.25 (SD = 4.47) for the control group and 24.60 (SD = 5.14) for the intervention group (ns). The length of stay was 35.71 days (SD = 22.62) for the control group and 47.44 days (SD = 28.00) for the intervention group, not a statistically significant difference.

Response

Response rate for both questionnaires was high. In the control group, 23 of 24 (96%) questionnaires were returned, 19 filled in by mothers (83%) and 4 by fathers (17%). In the intervention group 23 of 25 (92%) questionnaires distributed were returned, 16 completed by mothers (70%) and 7 by fathers (30%). The parents of three infants did not return the questionnaires, for various reasons, after being approached twice. One mother was very ill and moved to another city at that time, one mother could not find the time because of illness of her baby, and one mother refused to complete the questionnaire.

NICU-PSF Results

In this study, NICU-PSF questions concerning follow up were not included in the analysis as these questions were not yet relevant, because most children were still hospitalized when the parents completed the questionnaires. Open-ended questions were analyzed separately; 50 close-ended (sub)questions were also taken into analysis. The minimum possible score was 50 points and the maximum possible score was 243 points. The control group scored a mean of 174.04 (range: 136-217, SD = 20.98) and the intervention group 185.67 (range: 149-219, SD = 17.74), a statistically significant difference (Mann Whitney U-test = 154.5, p = 0.041). Almost all separate concepts also showed an increase in their mean scores; see Table II. Only the concept of preparedness showed statistically significantly difference, with the mean control versus intervention group being 13.83 versus 16.38 (Mann Whitney U-test = 162.0, p = 0.038). The concept of being a parent had a slightly lower mean score (9.39, SD = 1.73) in the intervention group compared to the control group (9.78, SD = 2.09) (ns).

Table II NICU-PSF scores according to control and intervention group

	Mean (SD)	
Concept	**Control group**	**Intervention group**
	N = 23	N = 23
Overall rating	26.17 (3.59)	27.50 (2.99)
Care of the baby	17.96 (3.42)	19.09 (4.02)
Communication with staff	46.22 (7.76)	49.59 (5.83)
Involvement in care	17.17 (5.20)	18.64 (5.13)
Being prepared	13.83* (3.81)	16.59* (4.52)
Support	20.78 (4.00)	21.52 (5.84)
Being a parent	9.78 (2.09)	9.39 (1.73)
Being near your baby	22.13 (2.77)	22.04 (3.35)
Total score	174.04† (20.98)	185.62† (17.74)

* Mann Whitney U-test =162, p = 0.038, † Mann Whitney U-test =154.5, p = 0.041

NPST Results

On the NPST, the control group had a mean total score of 4.10 (range: 3.00-5.00, SD = 0.59); the intervention group had a slightly but not statistically significant higher mean value of 4.26 (range: 3.71-5.00, SD = 0.37). The correlation between support (NPST) and satisfaction (NICU-PSF) scores was outstanding (r = 0.893).

Additional Analyses

We examined the correlations among scores on the NICU-PSF, NPST and NTISS score, the length of stay; and socioeconomic status. We found no significant correlations. As part of the intervention, behavioural observations were performed. The number of observations varied from 2 to 9 with a median of 4 observations per infant per admittance. There was no correlation between the number of behavioural observations performed and the scores on the NICU-PSF or NPST in the intervention group.

We also looked at possible differences in scores of fathers and mothers on the NPST and NICU-PSF. The total scores on both scales as well as the scores for the separate concepts of the NICU-PSF were comparable.

The open-ended questions of the NICU-PSF on positive experiences during the stay in the NICU were categorized. Parents of the control group most frequently mentioned the (unexpected) progress made by the infant, the gifts they received because of national holidays and pictures made by the nurses, and the stories nurses wrote in the infants' diaries. Parents also made some remarks on the kindness of nurses and their way of communicating with parents. The parents of the intervention group, however, remarked mostly on the support, involvement, interest, and honesty of the nurses and the explanation of behavioural observations. Some parents made a remark on the national holiday gifts and on the progress of their infant.

Parents of the control as well as the intervention group mentioned the set backs and medical complications of their infants as the major negative events experienced. Control group parents also mentioned negative experiences concerning transfer policies and communication around transfer and feelings of powerlessness. The intervention group mentioned several times the discrepancy between nurses in the way they handle the recommendations from the behavioural observations.

DISCUSSION AND CONCLUSION

Differences in characteristics (birth weight, and number of twins) between control and intervention group is a factor one needs to bear in mind when interpreting the results. Additionally, in the intervention group were three single mothers while all control group parents were either married or were living with partners. All factors mentioned could be of influence on satisfaction and perceived support. Another limitation is the translation

of the instrument. We did the commendable back translation, but we tested the Dutch version in a small (N = 3) sample only.

The response rates in our study are high (96% and 92%) and should be regarded as sufficient enough to give a valid impression of the opinion regarding satisfaction among parents in our NICU. A response rate of 60% for questionnaires is mentioned in literature as probably sufficient.[22]

In the literature, no cut off point is given for the NICU-PSF. We hypothesized that parents who experienced NIDCAP care would be more satisfied than parents who experienced traditional care. The high mean score of the control group made it difficult to improve. Considering that we have only just started with NIDCAP, we are content with the extent of improvement so far. We anticipate ongoing improvement of satisfaction rates will be seen within the next year after which a third satisfaction measurement will be scheduled.

Evaluating the separate concepts of the NICU-PSF, we expected changes in concepts like involvement in care and being a parent. These concepts can be seen as the measurement of the core concepts of NIDCAP. Only small changes in these concepts, however, were seen, probably because of the fact that parents adapted to the NIDCAP much faster than professional caretakers. Professionals had to go through a process of changing their attitudes. Nurses in particular needed some time to change, feel comfortable and become satisfied with the NIDCAP[23] (also J. M. Wielenga et al, unpublished data, 2004). Nurses reported feelings of intimidation because of parents telling them what to do, loss of control, and parents trying to take over.

The scores on the NPST reflected the small changes in satisfaction. The score was high in the control group as well as in the intervention group (4.10 vs 4.26). Miles et al found comparable mean scores in their study comparing Caucasian and Negroid women (4.19, SD = 0.56 vs 4.14, SD = 0.79).[14] According to them, the perceived support from the nurses suggests that parents are highly satisfied with their encounters with the nurses. It also indicates that the nurses are frequently perceived as providing emotional, informational, and esteem support and are perceived as giving a high level of care to their sick infant. The higher the parents rate the amount of support, the higher the satisfaction rates. With traditional care scoring as high as it did, it seemed almost impossible to expect a significant increase after implementing NIDCAP. This is complicated by the fact that satisfaction is measured among parents of infants receiving traditional care not knowing about other care possibilities.

Implications

As a result of this study, we became aware of areas needing improvement in nursing care. On the basis of the answers to the open-ended questions, we started quality improvement projects on better-preparedness to the transfer back to a regional hospital. We now evaluate each referral back. Furthermore, in weekly reflection sessions, the way nurses

handle and make choices in care are discussed to decrease the discrepancy between nurses and to teach them to see the infant as part of a family. Premji and Chapman[24] studied the experiences of nurses with developmental care. They identified "putting the baby first" as the basic social process used by nurses implementing developmental care. Considering that the developmental care model is clearly family focused, it remained unclear why these nurses still focused their attention almost entirely on the baby.[24]

The value of measuring parents' satisfaction in regard to NIDCAP introduction is increasingly important and necessary to document quality improvement. The transition to developmental care requires moving from a profession-centered approach to an approach involving shared decision making and responsibility in caregiving. Three major themes are involved with this shift: acknowledging the central role of the parent in the care of the infant, fostering the parent as a competent caregiver, and integrating the roles of coach, teacher and facilitator into the existing technically expert nurse role. Professionals in neonatal care need to be educated to perform these new roles.

The lesson learned is: With the introduction and consequently implementation of developmental care and subsequent improvement of parental satisfaction levels, the first activity to accomplish is giving a piece of the professional autonomy of nurses back to were it belongs, namely, to the parents, as concluded from the remarks made by nurses and parents in this study.

Changing the culture of care to family-centered individualized developmental care in the NICU is slow process; it is more of a journey than a destination. Measuring the progress of this quality improvement should be a continuous process. The results of this study, shortly after introduction of NIDCAP, are positive and encourage us to continue working according to NIDCAP.

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Chapter 8

A survey on job satisfaction among nursing staff before and after introduction of the NIDCAP model of care in a level III NICU in the Netherlands

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ABSTRACT

Purpose To study the effect of introduction of the Newborn Individualized Developmental Care and Assessment Program (NIDCAP) on job satisfaction of nursing staff.

Subjects Registered nurses, with specialist neonatal qualifications or in training, in a level III Neonatal Intensive Care Unit (NICU) in the Netherlands.

Design and Methods A survey was performed before (2001) and six months after (2003) introduction of NIDCAP as the new model of care. Job satisfaction was measured by means of The Index of Work Satisfaction (IWS).

Principal Results From the 74, respectively 70 nurses on the payroll, before and after introduction of NIDCAP, 67.6% and 80% responded. No differences were seen in background variables between both groups. Individual components of the IWS on importance as well as satisfaction were ranked in the same order before and after NIDCAP introduction. The results on the IWS demonstrated no change in the overall satisfaction rate, respectively 14.4 and 14.5. Only in one component, organizational policies, the mean score increased statistically significant (3.68 and 4.13 respectively, $p = 0.008$). The other component scores did not increase significantly.

Conclusions Major changes in nursing care practice by means of NIDCAP, in our neonatal intensive care unit did not affect overall satisfaction. Scores suggested nursing staff to be persistently satisfied about their job.

INTRODUCTION

The Newborn Individualized Developmental Care and Assessment Program (NIDCAP) is introduced, and used increasingly in Neonatal Intensive Care Units (NICU's) to improve developmental outcome of preterm infants.

NIDCAP is based on the Synactive Theory of Development.[1,2] The basic assumption of this theory is the competence of the newborn infant. This is conceptualized as the degree of smoothness and modulation, regulation, and differentiation of the five different subsystems of functioning: autonomic, motor, state regulatory or state organizational, attentional/interactional and self regulatory system.[1,2] These subsystems mature simultaneously and have a synergistic influence on each other throughout development. Infant's behavior can be observed in a systematic way and provide the basis for the estimation of the infant's current goals in development. Recommendations for support of infant's development to reach these goals concerning the physical environment in the NICU for infant and family, the timing and organization of appropriate interventions, the support of the parents' in supporting their infant's development and the coordination of care delivered by special service providers.[1,2] NIDCAP has been subject of several studies in the United States as well as in Europe. It has been reported to decrease the requirement of ventilatory assistance, oxygen supply and length of stay, enhancing weight gain and improving long-term development.[3,4]

In 2001 preparations were started to introduce NIDCAP as the new model of care in the NICU of the Emma Children's Hospital / Academic Medical Center, a 28 bed level III unit in Amsterdam, the Netherlands. At that moment the NICU had a shortage and high turnover of nursing staff. In the first half of 2001 the NICU had a quantitative shortage of nursing staff of around 12%. From the 80.6 Full Time Equivalents (FTE) 70.8 were occupied. The turnover was high; experienced nurses left for various reasons and only a few new nurses were recruited. Moreover, there was a mean absence of 16% due to illness (pregnancy excluded).

While in literature numerous factors have been linked to nurse turnover, low job satisfaction is most frequently cited.[5-9] Literature on job satisfaction among nurses agreed on job satisfaction as the key factor in nurses' turnover and job satisfaction was suggested to be related to organizational, professional and personal factors.[5-11] A framework connecting organizational and personal factors, work environment and patient outcome with job satisfaction was suggested in literature.[12] One of the factors influencing such a framework was identified as the model of care delivery.

We hypothesized that changing care into care according to NIDCAP principles could affect job satisfaction of the current nursing staff of our NICU. Job satisfaction in relation to changing work conditions according to NIDCAP has not been studied in detail. In one study staff was asked, one year after NIDCAP implementation, to express their opinions on the impact of NIDCAP by using a survey with statements which were developed for

this purpose.[13] Two items referred to job satisfaction; "my working conditions in general have become worse/unchanged/better when compared to conventional care" and "my satisfaction with my work in general has become worse/unchanged/better when compared to conventional care". Despite the demand for changes in the environment (sound, light and activity) and the way of caregiving involved, the staff experienced an improvement in their working conditions and enhanced job satisfaction. However, statistics were not provided.[13] The same questions were asked in another a study, four years after implementation started, and showed no change in working conditions or satisfaction.[14]

Others studied satisfaction in relation to sound and light modifications in the environment and found staff to be highly satisfied (86% pro) with reductions in sound levels and a mixed (61% pro and 35% con) reaction to reduced light levels.[15]

Both quantitative studies focused mainly on satisfaction due to environmental changes but NIDCAP is supposed to change more than the physical environment. It changes organizational structures, the philosophy, planning and delivery of care, attitudes of professionals and relations between family and professionals as well. Other studies have been performed on experience and opinions of nursing staff regarding NIDCAP or developmental care and implementation or training. However, these studies did not address job satisfaction.[16-18]

A study on utilization of nursing research in the NICU used developmentally supportive care (operationally defined as modification of the physical environment) as the clinical focus for the study.[19] This study used the Index of Work Satisfaction (non revised edition) and found a statistical significant difference in the score for job satisfaction. Scores on subscales increased statistically significant (autonomy, task, nurse/nurse interaction), or increased but not significant (organizational policies, professional status and pay) over the course of the study.

The aim of the study presented here was to explore if NIDCAP introduction affected job satisfaction of the nursing staff in our level III neonatal intensive care unit.

METHODS

Study design

A pre- and post- survey using a self-administered questionnaire was used to assess job satisfaction before and shortly after introduction of NIDCAP to answer the following research question: Are nursing staff members satisfied with their job after the introduction of NIDCAP in our level III neonatal intensive care unit?

Sample and Setting

Job satisfaction was assessed twice in a sample of Registered Nurses (RN) with specialist neonatal qualifications or in training for this qualification.[20] This study was carried out in the level III NICU of the Emma Children's Hospital / Academic Medical Center, a teaching and referral hospital in Amsterdam, the Netherlands. Around 500 preterm infants with a gestational age of ≥ 25 weeks were admitted to the NICU per year. The 28 bedded NICU has three units, 2 intensive care units, with 10 beds each, and 1 post intensive care unit of 8 beds.

All RN's on the payroll of the NICU on August the 1st 2001 (N = 74) were asked to voluntary participate in the pre-survey. NIDCAP was introduced in the last trimester of 2001. A post- survey was performed, six months after introduction of NIDCAP, among all RN's on the payroll on May 1st 2003 (N = 70). All RN's received a questionnaire in their mailbox at work and were asked to complete this questionnaire within 3 weeks. It required 30 minutes to complete the questionnaire. A written follow-up reminder was sent to all potential subjects, at the end of this three weeks period and again two weeks thereafter.

Demographics, personal or descriptive items other than age, gender and years of experience were not collected. The target was the nursing staff as a group and not specific subgroups.

Completing the questionnaire was seen as consent. The Research and Ethics Committee approved this study.

The NIDCAP Introduction Path

A multidisciplinary taskforce identified the need for change from basic to a higher level of developmental care consisting of a plan for integration of the concepts and philosophy of NIDCAP into the nursery environment in terms of organizational policies and practices. The availability of necessary resources was considered. Alliances among all disciplines (nurses, doctors, physical therapists, social worker and psychologist) involved in the care of the preterm infant and the parents were build to guarantee involvement of all. Plans were conceptualized in collaboration with a research group set up for the embedding of NIDCAP introduction in a scientific context.

When the pre-survey was conducted, infants received the standard care practiced at the NICU at that time. The underlying principal of the nursing care system in our unit was primary nursing. Two nurses, due to part time working factors, had a shared responsibility towards one patient and were the care planners as well as the principal caregivers. As far as managing work and care concerns it was a non hierarchical unit, responsibilities were shared and head nurses provided logistic necessities and coordinated patient flows.

Care included encouragement of skin-to-skin holding (kangaroo care), promoting breastfeeding, early use of clothing in the incubator, use of sheepskins, hammocks, provision of pacifiers and stuffed animals or toys. Making a diary was a common habit

as well. Parents were motivated to take part in daily care procedures as much as possible and were allowed to come to their infant 24 hours a day.

After the pre-survey was conducted, five registered nurses with specialist neonatal qualifications, including a nurse educator responsible for the specialist neonatal qualification course, started NIDCAP training. All professionals (nurses, doctors, physical therapists, laboratory personnel, social workers) involved in neonatal care in our NICU, were educated by means of a one day NIDCAP Introductory Course, lectured by an official NIDCAP trainer. The NIDCAP was introduced gradually in the nursery starting October 2001. The project leader, already NIDCAP certified, gave training on the job in recognizing signs and signals of the preterm infants to different types of handling. Sound, light, activity, handling and positioning were subject of several discussion meetings. The NIDCAP trainer facilitated the above mentioned processes.

Changes took place gradually and on an evolving basis. After certification of the five nurses, we introduced NIDCAP in a specified study group of infants. Infants born before thirty weeks of gestation and their parents received NIDCAP. The NIDCAP consisted of the Naturalistic Observation of Newborn Behavior (NONB), the behavioural observation belonging to the NIDCAP.[1,2] The observer observed the infant for 60-90 minutes but had no interaction with the infant. Included were a 10 minutes pre-activity observation and at least a 20 minutes post activity observation period. A caretaking interaction was observed, like suctioning, diaper change, feeding session or blood sampling. A case report was written assessing the infants' current ability to organize and modulate the five subsystems, following the observation. The case report consisted of several standard parts: introduction, description of the nursery environment, the behavior of the child before, during and after caregiving interaction, a summary consisting of the medical history, the last 24 hours and the present behavioural functioning and the current goals of the infant. Adjustment and individualization of care and environment based on the observation and caregiving recommendations to support the individual infants' development were formulated. A developmental care plan was based on the case report. Recommendations and care plan were discussed with the parents, the professional who was observed in interaction with the infant and the primary nurse.

The observations started within 3 days after birth and were repeated every 7 to 10 days thereafter or when major changes had occurred. The NIDCAP certified nurses were responsible for the consistency and adherence of the developmental care plans provided. The NIDCAP intervention was provided until discharge of the NICU.

Sessions of reflection with all professionals present were held twice a week from the start of the project onwards. Sessions of reflection were facilitated by the project leader. In these sessions experiences resulting from changing practice into NIDCAP were exchanged and discussed and one was seeking to answers and solutions to questions or problems through exploring one's thoughts, feelings, choices and actions.[21]

Outcome and Measure

Job satisfaction assessment was done using the Index of Work Satisfaction (IWS revised edition) developed specially for nurses, widely used and the best available tool at that moment.[6] The IWS is designed to measure factors within the scope of the organization, and the components included are designed to measure a variety of factors that are central to the perception of satisfaction, providing information that could be of practical use of management.

The IWS is a two-part tool to measure nurses' expectations (importance) and satisfaction with each of 6 job components: pay, autonomy, task requirements, organizational policies, interaction, and professional status (Figure I). Internal consistency of the IWS has been well documented (Cronbach's alpha 0.82, Kendall' Tau 0.92).[6] The construct validity of the IWS is documented by means of factor analysis and individual one-way ANOVAs, all components were significantly related to the overall scale at <.0001 level of significance.[6]

Figure I Index of Work Satisfaction Components

Pay -- dollar renumeration and fringe benefits received for work done
Autonomy -- amount of job-related independence, initiative, and freedom, either permitted or required in daily work activities.
Task Requirements -- tasks or activities that must be done as a regular part of the job
Organizational Policies -- management policies and procedures put forward by the hospital and nursing administration of this hospital
Interaction -- opportunities presented for both formal and informal social and professional contact during working hours
Professional Status -- overall importance or significance felt about your job, both in your view and in the view of others

(With permission of P. Stamps)

In the first part (part A) of the IWS expectations regarding 15 paired comparisons (see for example Figure II) are rank ordered; weighted values are calculated to reflect the importance of each component (scoring range 1-7). For part B of the IWS regarding satisfaction, scores for each component (6 to 10 statements per component, 44 statements in total). A 7 point Likert attitude scale (1 reflecting strongly agree to 7 reflecting strongly disagree) was used for measurement (see for example Figure III). This total scale score (range 44–308) estimates the unweighted level of satisfaction. In order to have weighted scores, the IWS index itself must be calculated (range 0.9–37.1) representing the overall summary of level of satisfaction.

The IWS was translated into Dutch by the research group and translated back into English by an independent bilingual nurse educator and was sent to the author for approval. Approval and permission to use the IWS was granted by Stamps.

Figure II Example Part A of the Index of Work Satisfaction

Part A (Paired Comparisons)

Please choose the one member of the pair, which is most important to you.

1.	☐ Professional Status	or	☐ Organizational Policies
2.	☐ Pay Requirements	or	☐ Task Requirements
3.	☐ Organizational Policies	or	☐ Interaction
4.	☐ Task Requirements	or	☐ Organizational Policies
5.	☐ Professional Status	or	☐ Task Requirements
6.	☐ Pay	or	☐ Autonomy

(With permission of P. Stamps)

Figure III Example Part B of the Index of Work Satisfaction

Part B (Attitude Questionnaire)

Please circle the number that most closely indicates how you feel about each statement.
The left set of numbers indicates degrees of agreement.
The right set of numbers indicates degrees of disagreement.

		Agree						Disagree
1.	My present salary is satisfactory.	1	2	3	4	5	6	7
2.	Nursing is not widely recognized as being an important profession.	1	2	3	4	5	6	7
3.	The nursing personnel on my service pitch in and help one another out when things get in a rush.	1	2	3	4	5	6	7
4.	There is too much clerical and "paperwork" required of nursing personnel in this hospital.	1	2	3	4	5	6	7
5.	The nursing staff has sufficient control over scheduling their own shifts in my hospital.	1	2	3	4	5	6	7
6.	Physicians in general cooperate with nursing staff on my unit.	1	2	3	4	5	6	7

(With permission of P. Stamps)

Data Management and Statistics

Data was statistically evaluated using SPSS 12.0 software (SPSS, IL, USA). For part A from the IWS, importance score, a frequency matrix was created, a proportion matrix developed, numbers transferred to z values and a constant added to produce positive values conform the scoring workbook accompanying the IWS.[22] Components were ranked according to relative importance. For part B, satisfaction, percentages were calculated for

each response option in each statement and scores on the 6 scale components were calculated. To calculate the Index of Work Satisfaction, component scores on importance (part A) were multiplied with component scores on satisfaction (part B), summed and divided by six (the number of components).

Descriptive statistics were used for participants' characteristics and IWS statements. Chi squared test, t-test, Fisher's exact test or Mann Whitney U-test was applied for group comparisons, when appropriate.

RESULTS

The response at baseline was 67.6% (50 of 74 nurses) and two years later after introducing NIDCAP 80% responded (56 of 70). From the 74 nurses on the payroll at the first measurement, 61 were still present during the second measurement; nine nurses were new on the payroll at the second measurement. All nurses on the payroll had a western ethnical background. There were no significant differences in mean age (range, SD) before and after introduction of NIDCAP, respectively 38.7 years (23-59, 8.2) and 39.4 (22-54, 8.7) ($p = 0.708$) or in age categories ($p = 0.553$) (Table I). There were no differences in gender between both groups. The mean (range, SD) number of years of working experience in the NICU differed before and after introduction of NIDCAP respectively 6.8 (0-26, 6.6) and 8.3 years (0-26, 6.8) but not significantly ($p = 0.079$) as shown in Table I. The group had the same consistency regarding educational levels at baseline and after introducing NIDCAP; 4% versus 6% head nurses, 84% versus 86% RNs with specialist neonatal qualifications and 12% versus 8% RNs in training for specialist neonatal qualifications ($p = 0.417$).

The level of satisfaction of the nurses was determined by calculating importance scores first. This resulted in the following order of job satisfaction components, from high to low: autonomy, interaction, pay, professional status, task requirement and organizational policies. After introducing NIDCAP, the nurses ranked the components in the following order autonomy, interaction, pay, task requirement, professional status and organizational policies, no statistically significant differences were seen (Table II). The values of the levels of importance of each component are shown in Table II.

Satisfaction scores (Part B) are ranked in a somewhat different order compared to importance scores, from most to least satisfied: autonomy, professional status, interaction, task requirements, organizational policies and finally pay. The ranking at baseline and after introducing NIDCAP were exactly the same (Table II). However, scoring on the individual component of organizational policies improved significantly, mean score 3.68 vs.4.13 points ($p = 0.008$) after NIDCAP introduction. Total scale score (all 44 items together) increased from 205.4 to 208.5 which was not significant.

Table I Characteristics of Nurses on the Payroll

	Baseline (N= 74)	After introducing NIDCAP (N=70)	p
Mean Age [years (range, SD)]	38.7 (23-59, 8.2)	9.4 (22-54, 8.7)	0.708
< 30 years of age	12%	16%	
30 – 39 years of age	42%	31%	0.553
40 – 49 years of age	35%	37%	
≥ 50 years for age	11%	16%	
Gender (f/m)	72/2	67/3	0.675
Mean Working Experience NICU [years (range, SD)]	6.8 (0-26, 6.6)	8.3 (0-26.6.8)	0.079
< 1 year	12%	9%	
1 – 5 years	46%	37%	
6 – 10 years	12%	20%	0.590
11 – 15 years	15%	16%	
≥ 15 years	15%	18%	
Educational level			0.417
Management	4%	6%	
RN*	84%	86%	
RN in training†	12%	8%	

*registered nurse with specialist neonatal qualifications
†registered nurse in training for specialist neonatal qualifications

The IWS index was calculated, representing both the level of importance and the current level of satisfaction. The IWS at baseline was 14.4 and after introducing NIDCAP the IWS was 14.5, which is not statistically significantly different.

At the level of individual statements, 7 statements differed significantly ($p < 0.05$) between baseline and after introduction of NIDCAP. Belonging to the component professional status "Nursing is not widely recognized as being an important profession" (respectively 3.04 vs. 3.96, $p = 0.005$). Within the component task requirements "I have sufficient time for direct patient care" (respectively 5.86 vs. 5.14, $p < 0.0001$) in favour of the baseline measurement, "I think I could do a better job if I do not have so much to do all the time" (respectively 5.10 vs. 4.45, $p = 0.042$) and "I have plenty of time and opportunity to discuss patient care problems with other nursing service personnel"(respectively 5.54 vs. 4.95, $p = 0.033$). Within the component autonomy "I have too much responsibility and not enough authority" (respectively 5.88 vs. 5.41, $p = 0.010$. "There are not enough opportunities for advancement of nursing personnel at this hospital" (respectively 3.84 vs. 4.54, $p = 0.033$), part of organizational policies. Within the pay component "From

Table II Importance and satisfaction scores measured with the Index of Work Satisfaction

Component	Importance (Part A)* Mean Score†		Satisfaction (Part B) Mean Score†	
	Baseline (N = 50)	after NIDCAP (N = 56)	Baseline (N = 50)	after NIDCAP (N = 56)
Autonomy	3.98	3.78	5.45	5.48
Pay	3.38	3.39	3.00	2.76
Professional Status	2.77	2.77	5.2	5.46
Interaction	3.57	3.49	5.13	5.32
Task requirements	2.60	2.88	5.00	4.65
Organizational policies	2.30	2.35	3.68	4.13‡

* Importance scores are calculated by adding the number of times each component is rated more important than a paired component, dividing by the number of respondents to create a frequency matrix. From this number a proportion matrix is developed, transformed to z values, and a constant added, resulting in a positive value for each component (range 1-7)
† Total satisfaction score divided by number of statements in each component (range 1-7).
‡Mann Whitney U-test= 984.5, p=0.008

what I hear about nursing service personnel at other hospitals, we at this hospital are being fairly paid" (respectively 3.12 vs. 2.58, p = 0.041).

Although it was not the subject of the study we were curious what had happened with rates on absence and shortage of nursing staff. The absence due to illness decreased from 16% to 10.5% in the period after introducing NIDCAP and the shortage of staff decreased from 12% to 10%, due to a decrease of part time factors among the staff. However, these differences were not statistically significant.

DISCUSSION

The response rate in this explorative study was adequate, respectively 67.7% and 80.0%. Response rate of 60% for questionnaires is considered sufficient to give a valid impression of the opinion towards a topic in this case job satisfaction among nursing staff in our NICU. [23] In a survey on 30 studies using the IWS as measurement tool response rates varied from 10 to 100% with a mean of 59%.[6] One of these studies was amongst NICU personnel which had a response rate of 75%.[6]

Results from this study suggested that introducing NIDCAP does not affect the overall level of job satisfaction among nurses in the time span of almost two years as used in this study. It was of clinical relevance to us that the calculated IWS index scores in this study (14.4 and 14.5) suggested that nurses in our setting were persistently satisfied about their jobs. From the previous mentioned survey it appeared that the most common IWS index value is around 13.[6] Only two studies showed a score higher than 14.[6]

An additional factor contributing to the absence of more striking findings may be that job satisfaction could be influenced by (unknown) external factors such as work-to-family and family-to-work conflicts, demographic characteristics, personality.[11] Consequently, the activities at the unit level may not be strong enough to overcome the (negative) effects from these external factors.

Satisfaction is a multifaceted phenomenon, so one has to look beyond the IWS index itself and look at the level of satisfaction represented by the mean scores for each component.

Autonomy was rated the most important and the most satisfying component. Introducing NIDCAP gave the nurses less latitude to make decisions for their patients on their own knowledge and experience, due to the fact that NIDCAP trained professionals took over a part of the autonomy by providing them with recommendations for care and support of the development. Dealing with this shared autonomy due to the presence of a new (NIDCAP trained) professional should be an item of reflection. Change in autonomy is visualized in the statement of the nurses to have too much responsibility and not enough authority, significant more nurses agreed with this statement after NIDCAP introduction. However, the satisfaction score on autonomy did not change by introducing NIDCAP. Looking at data of comparable studies using IWS, the earlier mentioned survey and a second survey using the IWS among 4 Canadian acute care hospitals (1 for children) the score on this component in our study was rather high, 5.45 compared to both surveys (4.7 and 4.68).[6,12]

Interaction was ranked as the second most important component. Within primary nursing interaction among nurses and between nurses and medical doctors was already an important issue. NIDCAP introduction added the dimension of interaction between nurses and NIDCAP trained professionals (also nurses in our case). Satisfaction scores increased after NIDCAP introduction pointing in the direction of positive judgment of this dimension of interaction added. Comparative data from both surveys (4.7 and 4.83) illustrating the score to be somewhat high, 5.13. [6,12]

Pay is a component which can not be influenced by changing the model of care. Pay, in the Netherlands, depends on appointments of the national government with the association of academic hospitals and the unions. Pay is for that reason not discussed any further.

Professional status was not ranked as a very important component. Nurses were satisfied with their status as was reflected in the satisfaction being one of the highest scores. During the study in the media (television, radio, newspapers) extensive attention was paid to the introduction of NIDCAP pointing out the importance of the role of neonatal nursing and neonatal nurses. This might be an explanation for the significant difference, reflecting more disagreement on the statement of nursing not being widely recognized as an important profession and consequently on the increase of the component of professional status (from 2.77 to 5.25). However, in the surveys comparable scores were shown, 5.3 and 5.26.[6,12]

Task requirements was ranked as rather unimportant compared to the other scale components. Nurses were a little less satisfied about their tasks requirements. NIDCAP introduction brought about a major shift in the tasks and activities of nurses from care based on routine to care based on the signs and signals of the infant and from task based to relation based care. Most care was performed with two nurses, one nurse performing the care and one nurse comforting and containing the infant. Nurses had to leave schedules and had to change to performing care that was based on the needs of the infant and family. Furthermore nurses had to consider recommendations, made by the NIDCAP trained nurses and were no longer able to perform tasks and activities as they used to do. Longer periods of not performing patient related activities became more common with the introduction of NIDCAP.

Introducing NIDCAP resulted in significant differences on the level of statement scores. There was more agreement with the statement on having enough time for patient care and less disagreement with the statement on doing a better job in relation to the amount of work. The score on the statement of having plenty of time to discuss patient care problems with nursing colleagues reflected more disagreement after introduction of NIDCAP. Despite the reflection sessions on NIDCAP twice a week, the nurses were not satisfied with the amount of time available. More time for discussion and reflection was needed. The reason for finding this disagreement could be that the process of change is a time consuming one. So, it is possible that the scores reflect the process of change rather then how satisfied nurses were with their new package of tasks and activities.

Organizational policies was scored as the least important component. However, it was the only component with a statistical significant increase after NIDCAP introduction. All statements of this component had about the same scores before and after NIDCAP introduction except for one. The statement on not enough opportunities for advancement was statistically significant more disagreed with. New educational possibilities as the NIDCAP training for the nurses are likely the cause of this change. Nurses were much more satisfied with the organizational policies (3.68) compared to the nurses in the two surveys (3.4 and 2.94).[6,12]

LIMITATIONS

The limitation of a survey is that the information obtained with a survey tends to be relatively superficial. Despite the excellent response rate the potential for non-response bias exists, we were not able to compare characteristics of respondents and non-respondents because of the anonymous questionnaires.

Performing a pre- and post-survey over a time period of several years there is always the risk of the uncontrollable natural course of nursing staff changes as appeared in this study, and aging resulting in comparing not completely identical group situations. Due to the fact questionnaires were anonymous and irreducible we were not able to restrict analysis to nurses responding to both surveys.

The relationship between nurse and job satisfaction may also be affected by personal circumstances. It is possible that the period of time between our two moments of measurement was too short to capture the nurses' satisfaction with the new model of care. Possibly, feelings regarding change in it self were measured. A third measurement after full implementation would be worthwhile. However, the IWS has restrictions due to its character; it reflects the level of satisfaction of the individual nurse instead of the nursing staff as a group. Recently the IWS was adapted to change the focus from the individual RN to the unit RN work group. For example, "I have sufficient time for direct patient care" now is "Nurses with whom I work would say that they have sufficient time for direct patient care". The item focus on the workgroup is logically congruent with and supports interpretation of the unit-level nurse satisfaction score, which is calculated by aggregating individual RN scores on the survey.[24] The clinimetric properties of the adapted version have not yet been studied.

Since this study involved only one organization, generalization of results beyond this setting may be questioned.

CONCLUSION

This study provides a first exploration of the effects of introducing NIDCAP on satisfaction of the nursing staff in a NICU. Clinical significant findings have emerged. We showed that overall satisfaction levels of the nurse group were not significantly affected by introduction of NIDCAP. Secondly, four out of six components showed an increase in mean satisfaction scores and one increased statistically significant (organizational policies), only one component (task requirements) had a decreased mean satisfaction score.

Taking in account that nurses in our setting were already reasonably satisfied about their jobs before NIDCAP introduction and knowing that the second measurement took place immediately after the introduction phase we expect satisfaction scores to increase after completing full implementation of NIDCAP, which can take more than five years. These findings re-emphasize the interest of measuring nurse job satisfaction before and during an implementation project of a care model to be able to adjust the implementation route if necessary.

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Chapter 9

Discussion

The core of this thesis was to gain insight in the extent of stress and measurement of stress and discomfort in preterm infants and to explore new ways to reduce stress factors for preterm infants in the Neonatal Intensive Care Unit (NICU) by Newborn Individualized Developmental Care and Assessment Program (NIDCAP) implementation. Furthermore we evaluated the results of NIDCAP implementation on clinical, developmental and growth outcome. We also evaluated the satisfaction of parents and the nursing staff following NIDCAP implementation.

The purpose of this final chapter is to discuss the results from the separate study objectives, as mentioned in chapter 1, to discuss methodological issues, integrate the results and give suggestions for further research and clinical practice.

OBJECTIVES

The first objective was to evaluate whether the Comfort scale can be validated to assess stress and discomfort in preterm infants.

We found (chapter 2) that the Comfort scale is a valid and reliable instrument for use in ventilated preterm infants. The Comfort scale is also able to discriminate between the presence and absence of stress. The cut off point of 20 points with high sensitivity and fair specificity is chosen to prevent a false negative test result, meaning an infant mistakenly classified as not suffering from stress. Stress appeared to still be a real problem in our unit, 27% of the ventilated preterm infants had to deal with stress despite the fact they received routine morphine. This underscores the necessity of proper evaluation of stress in preterm infants. We prefer to use the Comfort scale for the evaluation of stress above clinical judgement because the Comfort scale is a more explicit formulation of the clinical judgement. It is obvious that clinical judgement is never free from subjectivity.

The Comfort scale being a non-intrusive objective observation, fits very well in the stress-preventing policies of todays care of preterm infants in the NICU. The use of the Comfort scale takes little time, 2 minutes for the observation and 1 minute filling in the score, three to six times a day. This can be easily integrated in the daily caregiving of preterm infants.

The second objective of study concerned the applicability of the Comfort scale in studying different modes of mechanical ventilation in relation to stress.

We found (chapter 3) high percentages of scores ≥ 20 points (34.5%) during the first three days of mechanical ventilation although we found no indication that this was influenced by the choice of ventilation mode (high frequency or conventional ventilation).

The study took the edge off the impression among nurses that the impressive vibrations of the tiny bodies were an additional source of stress for the infants. The

Comfort scale showed that our clinical observation, concerning stress, was not accurate. The current use of analgesics and sedatives seemed insufficient to prevent high stress scores. A recently published Cochrane review found insufficient evidence to support a recommendation for the routine use of opioids during mechanical ventilation.[1] It has been suggested that opioids should be used selectively, based on clinical judgement and evaluation of pain indicators.[1] When pain relief is required, morphine is recommended over midazolan because of fewer adverse effects.[1] However there is a need to investigate this issue, specifically in preterm infants. For now we recommend assessment of stress, by means of the Comfort scale on a routine basis during mechanical ventilation.

The Comfort scale has been adapted by adding an item on crying for non ventilated 0 to 3-year-old infants.[2] This adapted version, the Comfort behaviour scale, has been tested (the item of respiratory response and blood pressure excluded) recently for its use on heel puncture in preterm infants with a gestational age between 28 and 37 weeks.[3] Good interrater reliability was found for most items (weighted kappa ranged from 0.62 to 0.84), except on facial tension (weighted kappa 0.45) and muscle tone (weighted kappa 0.53). The intraclass correlation coefficient for the total score was 0.93 (95% CI: 0.89 – 0.96). These results are comparable with our results in ventilated infants. The cut off of 17 points was chosen for this 7 item version of the adapted Comfort scale based on an area under the curve of 0.97 (sensitivity 93.0% and specificity 80.0%).[3]

The Comfort scale measures the amount of actual stress. However to be able to use the observed infants' behaviour in the prevention of stress or to help the infant to cope with stress is a step further. Communication concerning infant stress (pain), recognizing behaviour as an expression of stress or discomfort, as well as the lag of assessment skills of professionals are described in literature as hampering factors in the care of very preterm infants.[4,5] Due to the inability of the very preterm infant to communicate verbally an extensive tool, based on behavioural items, is needed to be able to assess stress and consequently prevent it. The ability to identify behaviour, to interpret the meaning of that behaviour and to understand relationships between these behaviours, may help NICU caregivers to become more aware and sensitive of signs of stress in the infant. Caregivers who can accurately assess stress signals are more proficient at interaction with the infants and they are able to prevent moments of stress for the preterm infants.[6]

Although NIDCAP is not designed specifically to assess stress, a study on 24 of the movement items, has shown that a subset of eight movement behaviours are statistically significantly associated with pain.[7] Other studies showed that behavioural signs according to NIDCAP were associated with acute pain in preterm infants.[7,8] The conclusion of these studies was that the NIDCAP tool did not only assess stress, but also pain.[7,8]

NIDCAP and developmental care interventions also decreased pain scores significantly during interventions.[9,10] NIDCAP can be used as a tool to gain insight into pain and stress behaviour of the individual preterm infant as well as to help all caregivers including parents to become more sensitive and responsive to the infants cues, thus enhancing

mutual interaction. Caregivers become more attuned to the needs of the infant and can thereby provide adequate (i.e. neither too much nor too little) stimulation and prevent stress. Accordingly NIDCAP can be described as belonging to the new generation of interventions, which focuses on the interaction between the infant and caregiver.

A survey was performed to gain insight into care according to NIDCAP, being the new way of caring for preterm infants in Dutch speaking NICU's.

We found (chapter 4) a continuum of developmental care in Dutch speaking NICU's in the Netherlands and Flanders. At one side of this continuum some of the principles of developmental care based on initiatives of individual professionals were applied. No policy was formulated. A second group was formed by the majority of NICU's where the concept of developmental care was accepted. In these NICU's, developmental care existed from a set of resources and developmental care was part of the unit policy. This meant availability of facilities and support by the organization. The third group had committed themselves to apply developmental care according to NIDCAP and tried to establish individualized care based on behavioural observations. This group had a high level of expertise present.

The study showed there is consensus in the Dutch definition of the concept of developmental care as described in chapter 4. It is desirable to use the definition with the implementation process of developmental care in NICU's.

The study clarified that developmental care in whatever way, does not only have far-reaching consequences for the view and policy on care in preterm infants but also influences all the people individually taking part in this process i.e. nurses, doctors, paramedics with their expertise and parents. Developmental care leads to permanent changes in the way that NICU's are traditionally designed and organized.

The study showed developmental care and particularly NIDCAP apparently to be the new way of care for (very) preterm infants in the NICU's. A recent study came to the same conclusion.[11] That study reported developmental care (not specifically NIDCAP) to be perceived by neonatal nurses as the vital component to care provided in the NICU's.[11] A new dimension has been added to the expertise of the nursing discipline.

Until now there is limited evidence of the effect of NIDCAP on short term medical, neurodevelopmental and family outcome.[12,13-19]

The Cochrane review concluded that the effect of NIDCAP on neurodevelopmental outcome (measured in four out of the five trials included) was conflicting; in some trials a significant improvement on scores at 9, 12 and 24 months of age was found. In others no improvement on neurodevelopment could be demonstrated.[12,14,16-18] Family outcome was measured in only one trial, in which a significant group difference in family stress and perception of the child was found.[12,17] There was a number of overall design limitations of the trials included in this review. Because of the nature of the intervention, blinding was not possible and several studies reported on contamination of the control group with

developmental care practices. Meta-analysis was also limited due to the large variation in outcome or methods of measurement.[12]

Another meta-analysis, including 5 randomized controlled trials, as well as 3 phase-lag cohort studies concluded that there was inconclusive evidence to support the NIDCAP as a framework in which to provide developmental care. [20,13-16,21-24] Only a statistically significant improvement in days of requirement for supplemental oxygen was found. Also an improvement at 9 or 12 months was seen in neurodevelopment but not at 2 years. However, it should be noticed that three of the included studies were performed before the introduction of surfactant.[13,14,23]

The third objective in this thesis was to show that care according to NIDCAP improves the clinical outcome of the NICU stay of very preterm infants.

In our phase-lag cohort study (chapter 5) the effect of individualized developmental care (NIDCAP) and conventional care on short term clinical outcomes of preterm infants, admitted to a tertiary neonatal intensive care unit was compared. Interestingly, NIDCAP infants had a lower incidence of cerebral damage during the NICU period as compared to infants in the conventional care group. This effect could neither be explained by differences between both groups in the presence of cerebral haemorrhage at inclusion, nor by other differences in neonatal background characteristics, nor by a secular trend of lower cerebral damage incidence in our NICU. The fact that NIDCAP is aimed at a reduction of stress and a better match between environment and brain development might be an explanation. The fact that NIDCAP may have resulted in less severe cerebral damage, should be interpreted with precaution, since the number of patients included in our study was rather small. But in this respect and in line with others[25,26], we conclude that NIDCAP deserves further exploration.

Recently, preliminary short term outcome data from a large NIDCAP randomized controlled trial on very preterm infants was presented.[27] This study confirms the finding of significantly less mechanical ventilation, lower incidence of chronic lung disease and shorter hospitalization.

Care according to NIDCAP during the NICU period improves growth and developmental outcome during the first two years of life of preterm infants, was the fourth objective to be studied. We found (chapter 6) no effect of NIDCAP on the mental or psychomotor developmental outcome at the corrected age of 24 months compared to conventional care as measured with the Bayley Scales of Infant Development-II. At term age, NIDCAP group infants were still motor and autonomic (Neurobehavioral Assessment Scale [NBAS]) less stable compared to conventional care infants. No differences were seen in the neurological status (Touwen) or growth parameters during the first 24 months of age. Growth did not differ between the groups. Our study provided no evidence for a beneficial effect of NIDCAP on developmental outcome or growth. However, taking the

fragile status (NBAS scores) of NIDCAP infants into account, their equal developmental outcome at 24 months is remarkable.

The fifth objective was to evaluate if NIDCAP increases satisfaction rates of the parents of preterm infants. From the quality of care perspective improving satisfaction was an important issue. In our study (chapter 7) we showed parents to be statistically significant more satisfied (NICU- Parent Satisfaction Form [NICU-PSF]) with caregiving according to NIDCAP than the conventional care for their infants. No difference was seen in the amount of perceived support by nurses (Nurse Parent Support Tool [NPST]) of parents in both care groups.

In the literature a cut off point was given, neither for the NICU-PSF nor for the NPST. The principle of, the higher the score the more satisfied, was applied. However, with conventional care scoring as high as it was, it seemed almost impossible to expect a significant increase in satisfaction after implementing NIDCAP. Considering the fact that we have only just started with NIDCAP, we are content with the extent of the improvement so far.

A recently published study concluded in line with our results that mothers in the NIDCAP group, tended to rate the staffs' ability to support them in their roll as a mother somewhat higher, compared to the control group mothers.[28] Another study reported on parents having noticed, the positive experience and effects of wellbeing of their infant cared for by NIDCAP. However, that did not result in differences in parental stress between parents with infants cared for by NIDCAP or control care.[29]

The sixth objective of study, was the improvement of job satisfaction of the nursing staff caring for preterm infants with NIDCAP. We (chapter 8) showed that despite major changes in nursing care practice by means of NIDCAP did not affect overall satisfaction (measured with Index of Work Satisfaction [IWS]). It was of clinical relevance that IWS index scores suggested that nurses in our setting were consistently satisfied with their job.

NIDCAP also introduced a shared autonomy among nurses. NIDCAP trained professionals took over a part of the autonomy to make decisions for their infants based on their own knowledge and experience and by providing the nurse with recommendations for care and support of development. This shared autonomy did not influence the satisfaction score, autonomy was scored the most important and most satisfying component before as well as after introduction of NIDCAP.

Interaction was ranked as the second most important component. Within primary nursing interaction among and between nurses and medical doctors was already an important issue. NIDCAP introduction added the dimension of interaction between nurses and NIDCAP trained nurses, resulting in increased satisfaction scores on this component.

Nurses were satisfied with their professional status, which was reflected in the satisfaction score being one of the highest. However professional status was not ranked as an important component.

Nurses were a little less satisfied about their tasks requirements after the introduction of NIDCAP than before. NIDCAP introduction brought a major shift in the tasks and activities of nurses, from routine care based, to care based on the signs and signals of the infant and more important from task based to relation based care. It is possible that the scores reflect the process of change rather than how satisfied nurses were with their new job responsibilities and activities.

The organizational policies were scored as the least important component. However, it was the only component with a statistically significant increase after the NIDCAP introduction. This was mainly caused by the fact that there was statistically significant more disagreement on the statement of "not enough opportunities for advancement". New educational possibilities such as NIDCAP training for the nurses are likely to be the cause of this change.

The IWS reflects the level of satisfaction of the individual nurse instead of the nursing staff as a group. Recently the IWS was adapted to focus on the nursing group.[30]

A study on staff opinions, with respect to NIDCAP, reported nurses and doctors to be positive about NIDCAP in regard to the infants' wellbeing. However, NIDCAP was also thought to be time consuming and might worsen job conditions.[31] Nurses in that study had a more positive attitude and experienced a more positive impact of NIDCAP on the NICU conditions compared to conventional care.[31]

METHODOLOGICAL ISSUES

The studies described in this thesis concerned non-randomized comparisons. It is obvious that evidence-based practice, based on randomized controlled trials is highly preferable. In our opinion a randomization was not applicable for our studies on NIDCAP implementation. Since NIDCAP entails vigorous modification of nursing care that causes irreversible changes to caregivers' behaviour and environmental modifications, it therefore leads to the inevitable contamination of the control care. Unfortunately, a cluster randomized controlled trial in many NICU's nationwide was not an alternative option, since implementation of NIDCAP is expensive, labour intensive and time consuming. For this reason many NICU's were not able or willing to invest such an amount of money and time or had other priorities.

Randomized controlled trials are widely accepted as the most reliable method of determining effectiveness but most trials evaluate the effects of a single intervention. NIDCAP can be seen as a complex of different interventions, which may act both independently and interdependently and requires a different methodology for the

evaluation of its effects. Therefore the evaluation of the NIDCAP intervention is difficult because of the problems of developing, identifying, documenting, and reproducing the NIDCAP intervention. An iterative phased approach to the development and evaluation of the NIDCAP using different but complementary methods from quantitative research (descriptive studies, surveys, case studies) as well as from qualitative research (phenomological study, benchmarking, ethnographic studies) may be a more suitable approach to be able to come to a better understanding of a multidisciplinary approach of care, such as NIDCAP.[26,32.33]

NIDCAP can be seen as part of the environmental neonatology as introduced in the eighties. NIDCAP can be defined as the study on the effects of newborn intensive care facilities and micro environments on the growth, development, behaviour and health conditions of infants. NIDCAP has been thought to constitute an applied discipline in its own right.[34-36] NIDCAP needs a multidisciplinary approach from the perspective of social as well as medical sciences. Outcomes chosen to measure the effect of this intervention should be much more in line with social sciences such as, satisfaction, comfort and quality of life. With these social science outcomes one is able to look further than the facts of the usefulness of the intervention and value the intervention on its merits. NIDCAP should be placed in a broader perspective, when it is restricted to medical and developmental outcome, there is the risk of losing a very worthwhile intervention in the care of the preterm infants and their parents.

Our studies were hampered by another methodological issue. Groups were not similar with respect to background characteristics, as well as some clinical and socio economical characteristics. Differences were accounted for in multivariate analysis. However, due to the relatively small sample sizes in our studies, the number of variables that could be adjusted for, was limited.

The duration of the intervention period of NIDCAP (during NICU stay only) in this study is a matter of discussion. Comparison of our results with other studies is rather difficult since in the Netherlands infants are transferred to general hospitals as soon as intensive care is no longer required. Consequently NIDCAP care ended at discharge from the NICU because developmental care was not yet introduced in these hospitals at that time. In studies from other countries infants stayed in the NICU and received NIDCAP care until discharge from the hospital or at least until 36 weeks post conceptional age. The ideal length of the intervention is not yet known.

INTEGRATION OF RESULTS

Integrating the results described in this thesis and the methodological issues of studying developmental care, resulted in the following implications for further research and clinical practice.

Research implications

Research on stress should be focused on the measurement of stress and prevention of stress. Consensus in the use of the Comfort scale as the way to measure stress and pain for preterm infants would be a major step forward. Studies on adequate analgesic and sedation are still necessary especially during invasive treatment.

Further research on NIDCAP is needed to prevent developmental care to end up in science and history books just as a trend of the first years of the 21st century. NIDCAP deserves a chance to prove it is the preferred model and deserves a firm footing in the care for very preterm infants and their parents.

Performing a multi-center European (and North American) study combining quantitative and qualitative methodologies and medical, nursing and behavioural science viewpoints would be worthwhile and is highly recommended.

Besides medical outcome, evaluation should be focused on measurement of psychological and morphological changes in brain function, wellbeing and behaviour of infants and the wellbeing of parents. Standardization of outcome parameters, methods of measurement and consistent timing of assessment is necessary to at least be able to compare separate study results.[37] The influence of NIDCAP on working conditions and job satisfaction of professionals should be a standard item in research on NIDCAP.

For comparison of study results standardization is necessary for the scoring of type or level of developmental care interventions and the care environment, the duration of the intervention as well as the number of observations for each infant before performing further research on developmental care models as NIDCAP.

The cost of the NIDCAP intervention is considerable because of the need for specially trained personnel. The economic impact of the implementation and maintenance of developmental care practices should be evaluated. Economic evaluation which takes in account both the increased costs of the intervention and cost savings, resulting from possible lesser or shorter medical consumption by preterm infants, should be studied. Such an evaluation could be the answer to the question if we should invest our financial limited resources in NIDCAP.

The cultural context and beliefs in relation with developmental care and NIDCAP principles should be a topic in future research, especially in multicultural populations such as the metropolitan areas in the western part of the Netherlands.

Studying the continuity of individualized developmental care during NICU stay as well as during regional hospital stay should give more insight into the desirable length of the intervention. Also the combination of NIDCAP with other developmental intervention programs, in the first period after hospitalization, such as Infant Behavioural Assessment Intervention Program (IBA-IP[38-43]) should be studied to gain more information on the desirable period of developmental care.

Another aspect to study is the way preterm infants react after being cared for by NIDCAP compared to conventional care when the infant is challenged or triggered. Is the

behaviour of NIDCAP infants more organized, do they show less stress behaviour and is their regulation better compared to conventional care infants?

On the other hand it could be questioned if it is really necessary to scientifically prove that the obvious human care, with the evaluation of well-being and the application of structured gentle care to support a fragile preterm infant and its family, is better. Perhaps it would be more appropriate to prove a more active and invasive care is not harmful but required for the preterm infant compared to the more natural developmental care.[44] In case of equal suitability the human care is obviously preferred.

Implications for clinical practice

This thesis describes that clinical practice in the NICU should be integrated in a developmental care environment for infants and their parents, in combination with individualized developmental care, based on regular behavioural observations according to the NIDCAP model of care for the very preterm infants. All potential painful and / or stressful periods and events should be assessed with the Comfort scale and actions to prevent or minimize pain, stress and discomfort should be formulated in an individualized care plan.

In the future the developmental care in the NICU setting should ideally be continued with other age specific developmental care programs (i.e. IBA-IP), after the intensive care period, once the infants are autonomic stable and have moments of alertness, during the remaining hospitalization and first few months at home. A continuum of developmental care is desirable to support the quality of life of (very) preterm infants. It is important that the terminology used should be universal and related to the outline of the developmental care concept, as well as to the description of the level of developmental care and hence its place within the continuum of developmental care.

It is recommended that implementation of developmental care and NIDCAP will be performed by a multidisciplinary team, since it concerns all disciplines involved in the care of preterm infants. Within the actual implementation, the special place of the nursing discipline has to be determined, as the neonatal nurse is the backbone of the NICU. It is the neonatal nurse who works in collaboration with medical decision-making professionals, provides direct medical related care and engages and supports families of premature or critically ill infants. It is essential to understand the neonatal nurses' perception of barriers to provide quality care (developmental/NIDCAP care) because those at the bedside have a comprehensive appreciation of the infants needs and their perception is important to infant outcome.

It is also recommended to use the available expertise and knowledge of NICU's who have already implemented developmental care and NIDCAP. A model of site visits could be a way to be able to provide recommendations regarding developmental care policies, practical outline and necessary expertise to implement or to generate developmental care into a higher level, all based on the ambition of the NICU's being visited.

CONCLUSIONS

Despite questionable methodology issues and limited evidence of medical and developmental outcome, the findings of this thesis are encouraging. NIDCAP has been well received by the parents but also by the nursing staff. It is a very attractive concept from a human perspective. Despite the need of further research, it is reasonable to encourage NICU's to implement developmental care, preferably including individualized behavioural observations and at least assessment of stress and discomfort to prevent routines and structures which undermine the infants' health, wellbeing and neurological development as well as wellbeing of parents and to support infants in developing to their full potential.

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Chapter 10

Summary, samenvatting

This thesis describes the outcome of our studies on assessment of stress and discomfort in preterm infants. Furthermore it describes the implementation of the Newborn Individualized Developmental Care and Assessment Program (NIDCAP) as well as the evaluation of its results on clinical, developmental and growth outcome. We also evaluated satisfaction of parents and nursing staff following NIDCAP implementation.

Comfort scale

We validated the Comfort scale for its use in ventilated preterm infants. The clinimetric properties (criterion-related validity and interobserver reliability) were assessed and a first evaluation of the diagnostic properties (sensitivity and specificity) of the Comfort scale was performed. Criterion validity, assessed by correlating the Comfort scale with the traditionally used clinical judgment regarding the amount of stress, appeared to be good. The reliability of the separate items as well as the total Comfort scale score was very satisfying. The diagnostic quality of the Comfort scale appeared to be excellent and resulted in a cut off point of 20, meaning the infant is suffering from stress if the score is above 20 points. Therefore the Comfort scale appeared to be a valid and reliable measurement tool to assess the presence of stress in ventilated preterm infants.

The Comfort scale was then used to study if high frequency ventilation (HFV) was an additional stressor compared to conventional ventilation (CV). This was studied in a cohort of preterm infants with Respiratory Distress Syndrome. Infants received either HFV or CV based on existing unit protocols and were sedated with a standard dose of continuous morphine. Comfort scale scores between the groups were comparable, adjustment for baseline differences revealed no differences in scores. Strikingly a large amount of Comfort scale scores were indicating stress in both groups, 34.0% in the HFV group and 35.6% in the CV group. The current use of sedatives seems insufficient to prevent high stress scores. We recommend assessing stress by means of the Comfort scale on a routine basis during mechanical ventilation. Furthermore, to prevent stress, a combination of non-pharmacological interventions, sedative and analgesic medication is necessary. While sedative and analgetic policies need to be studied extensively as demonstrated in our study.

Newborn Individualized Developmental Care and Assessment Program

Following the measurement of stress, we explored developmental care and specifically the NIDCAP as a method to enhance infants' potential for normal development and to reduce the negative effect of their stay in the Neonatal Intensive Care Unit (NICU). Behaviour of the preterm infant is sequentially observed with this method. The observed behaviour is subdivided into five subsystems: autonomic, motor, state, attention/interaction and self regulatory system. Following the observation a case report is written assessing the infants' current ability to organize and modulate the subsystems. Subsequently recommendations for the adjustment of environment and care as well as providing individual appropriate interventions to prevent stress and to enhance development are applied.

Current practice

A survey on the current practice concerning developmental care was performed. Dutch speaking NICU's in the Netherlands and Flanders were surveyed with a questionnaire. The questionnaire contained five domains: Principles of Care, Concept Clarification, Facilities and Resources, Professionals and Expertise, Research and Future. There appeared to be consensus in the definition of developmental care but the outline of the concept as well as the availability of facilities and materials showed great diversity. Some NICU's had professionals with a high degree of expertise and special training (NIDCAP certified).

In Dutch speaking NICU's there appeared to be a continuum of developmental care. At one side of this continuum, developmental care initiatives of individual caretakers were applied. On the other side, developmental care according to NIDCAP principles characterized by individualized care, based on behavioural observation and available know-how was applied. In between developmental care with availability of materials, facilities, management support and a unit policy was applied.

Implementation

Implementation of NIDCAP started with the training and certification of five nurses as NIDCAP observers. All other NICU nursing and medical staff were introduced to theoretical principles and practical skills to be able to apply the NIDCAP intervention. Parents, nurses and doctors were coached by the five trained nurses to use the recommendations for adjustment of environment and care and individual interventions following the observation. The observations started within three days after birth and were repeated every seven to ten days or when major changes occurred and NIDCAP care ended at discharge from the NICU.

We studied short-term clinical outcome, development and growth, parent satisfaction and job satisfaction before and after NIDCAP implementation. Infants born with a gestational age of less than 30 weeks were included in a prospective phase-lag cohort study.

The study group consisted of 25 infants in the NIDCAP group and 26 infants in the conventional group. At study entry NIDCAP infants had a statistically significant lower birth weight, were more often small for gestational age, had smaller head circumferences and were less often multiples than conventional care infants. During NICU stay of the NIDCAP infants, two nosocomial infection outbreaks occurred, resulting in statistically significantly more infants developing pneumonia in the NIDCAP group.

Clinical outcome

After adjustment for the above mentioned differences, a statistically significant decreased risk for severe cerebral damage in favour of NIDCAP, was seen. No differences were observed in respiratory status, growth during NICU stay or length of NICU stay.

Developmental outcome

We did not observe an effect of NIDCAP on mental or psychomotor developmental outcome of surviving infants. After adjustment for group differences and known outcome predictors, also no differences were seen between both care groups. At term age NIDCAP infants were still autonomic and motor less stable compared to conventional care infants. No differences were seen in the neurological status or growth parameters during the first 24 months.

Parent satisfaction

Satisfaction of parents was assessed with two questionnaires, one for overall care in the NICU and another for perceived support by nurses. Parents were statistically significantly more satisfied with caregiving according to NIDCAP principles than they were with the conventional care for their preterm infants. The rates in perceived support by nurses were higher for parents in the NIDCAP group, but not statistically significant.

Job satisfaction

A pre- and post-survey was performed among registered nurses with specialist neonatal qualifications or in training for these qualifications, to assess the effect of implementing NIDCAP on job satisfaction of the nursing staff.

No differences were seen in background variables of participants between the pre- and post-survey group. Individual components of job satisfaction on importance were ranked in the same order before and after NIDCAP introduction. Satisfaction was ranked in the same order before and after NIDCAP introduction as well. The post-survey overall satisfaction index slightly increased compared to the pre-survey.

Scores suggested nursing staff to be repeatedly satisfied about their job. Major changes in nursing care practice by means of NIDCAP in our NICU hardly affected the overall satisfaction.

Methodological issues

The present studies concerned small sample size, non-randomized comparisons. NIDCAP can be seen as a complex intervention, made up of various interconnecting parts which may act both independently and interdependently and require a different methodology for evaluation of its effects.

Standardization of outcome parameters, methods of measurement and consistent timing of assessment is necessary to be able to compare separate study results and overcome the issues of non-randomization and small sample sizes, as in our study.

Our studies were hampered by another methodological issue, NIDCAP and conventional groups were not similar with respect to background characteristics, as well as some clinical characteristics. However differences were accounted for in multivariate analysis.

Finally, the comparison of our results with other studies was restricted, due to duration of the intervention period of NIDCAP during the NICU period. In the Netherlands infants are transferred to referral hospitals as soon as intensive care is no longer required. At that time developmental care was not common practice in referral hospitals.

Integrating the results from the studies described in this thesis, combined with the methodological issues of studying developmental care, resulted in the following implications for further research and clinical practice.

Research implications

Research on stress should be focused on the measurement, prevention as well as treatment of stress. Consensus on the use of the Comfort scale as the way to measure stress for preterm infants would be a major step forward. Studies on adequate use of analgesics and sedatives are necessary.

Performing a multi-center NIDCAP study, combining quantitative and qualitative methodologies as well as medical, nursing and behavioural science viewpoints, would be worthwhile and is recommended. Besides medical outcome, evaluation should be focused on the measurement of psychological and morphological changes in brain function, wellbeing and behaviour of infants, as well as wellbeing of parents and satisfaction of professionals.

Studying NIDCAP should also focus on the way preterm infants react after being cared for by NIDCAP when the infant is challenged or triggered. Is the behaviour of NIDCAP infants more organized, do they show less stress behaviour and how is their (self)regulation compared to conventional care infants?

Another aspect of study should be the desirable length of the intervention and the continuity of individualized developmental care through NICU stay as well as during their following regional hospital stay.

The cultural context and beliefs in relation to developmental care and NIDCAP principles should be a question to be answered in future research as well.

The economic impact of the implementation and maintenance of developmental care practice should be evaluated. Cost savings possibly resulting from less medical consumption by preterm infants should be studied to be able to answer the question, if we should invest our financial limited resources in NIDCAP.

Implications for clinical practice

A developmental care environment for infants and their parents, in combination with individualized developmental care based on regular behavioural observations according to the NIDCAP, for the very preterm infants should be integrated into clinical practice in the NICU. All potential painful or stressful periods and events should be assessed with the Comfort scale and actions to prevent or minimise pain, stress and discomfort should be formulated in an individualized care plan.

It is recommended to implement developmental care and NIDCAP with a multidisciplinary team, since it concerns all disciplines involved in the care of preterm infants. Within the actual implementation the special place of the nursing discipline, the backbone of the NICU has to be accounted for. It is also recommended to use the available expertise and knowledge of NICU's who have already implemented developmental care and NIDCAP.

Conclusions

Despite questionable methodology issues and limited evidence of medical and developmental outcome, the findings of this thesis are encouraging. NIDCAP has been well received by the parents but also by the nursing staff. It is a very attractive concept from a human perspective. Despite the need of further research, it is reasonable to encourage NICU's to implement developmental care, preferably consisting of individualized behavioural observations and assessment of stress and discomfort to prevent routines and structures which undermine the infants' health, wellbeing and neurological development as well as the wellbeing of parents and to support infants in developing to their full potential.

Dit proefschrift is een uiteenzetting van resultaten van onze studies naar stress en discomfort van de prematuur geborenen. De implementatie van het Newborn Individualized Developmental Care en Assessment Program (NIDCAP) wordt, evenals de resultaten hiervan op klinische-, ontwikkelings- en groeiuitkomsten, beschreven. Wij hebben zowel de tevredenheid van ouders als de werktevredenheid van verpleegkundigen na NIDCAP implementatie geëvalueerd.

Comfort schaal

De Comfort schaal werd gevalideerd voor gebruik bij beademde prematuur geborenen. De klinimetrische eigenschappen (criteriumgerelateerde validiteit en interwaarnemer betrouwbaarheid) werden bestudeerd en een eerste evaluatie naar de diagnostische eigenschappen (sensitiviteit en specificiteit) van de Comfort schaal werd uitgevoerd. Criteriumvaliditeit, vastgesteld door het correleren van de Comfort schaal aan het traditioneel gebruikte klinisch oordeel over de mate van stress, bleek goed te zijn. Zowel de betrouwbaarheid van elk afzonderlijk item als de betrouwbaarheid van de totale Comfort schaal score stelden zeer tevreden. De diagnostische kwaliteit van de Comfort schaal bleek excellent en resulteerde in een afkappunt van 20 (een score van hoger dan 20 punten wijst op stress). De Comfort schaal bleek een valide en betrouwbaar meetinstrument te zijn om stress vast te stellen bij beademde prematuur geborenen.

Vervolgens werd de Comfort schaal gebruikt om te onderzoeken of hoog frequente beademing (HFV) een additionele stressfactor is in vergelijking met conventionele beademing (CV). Dit werd bestudeerd binnen een cohort van prematuur geborenen met een Respiratoir Distress Syndroom. De pasgeborenen werden beademd met HFV of CV op basis van bestaande afdelingsprotocollen en gesedeerd met een standaard dosering continue toegediende morfine. Comfort schaal scores tussen beide groepen waren vergelijkbaar, corrigeren voor verschil in achtergrondkenmerken leverde geen verschil op in scores. Opvallend was het grote aantal Comfort schaal scores dat wees op stress, 34.0% in the HFV groep en 35.6% in de CV groep. Het huidige gebruik van sedativa lijkt hoge stress scores niet te voorkomen. We bevelen aan om tijdens de beademingsperiode, stress routinematig vast te stellen met de Comfort schaal. Om stress te voorkomen, is een combinatie van niet farmacologische interventies met sedativa en analgetica noodzakelijk. Studie naar het gebruik van sedativa en analgetica is nodig, zoals gebleken uit onze studie.

Newborn Individualized Developmental Care en Assessment Program

Naast het meten van stress hebben we de mogelijkheden van ontwikkelingsgerichte zorg, in het bijzonder de NIDCAP, onderzocht als methode om de mogelijkheden van de pasgeborenen op een normale ontwikkeling te versterken en de negatieve effecten van hun verblijf op de Neonatale Intensive Care Unit (NICU) te beperken. Met deze methode wordt het gedrag van de prematuur geborene herhaaldelijk geobserveerd. Het geobserveerde gedrag is onder te verdelen in vijf subsystemen: autonoom, gemoedstoestand, motorisch, attentie/interactie en zelfregulatie systeem. Na de observatie worden in een verslag de

mogelijkheden van de pasgeborene om de subsystemen te organiseren en te moduleren, vastgesteld. Vervolgens worden aanbevelingen voor aanpassing van omgeving en zorg gedaan en individueel geschikte interventies gegeven ter preventie van stress en ter ondersteuning van de ontwikkeling.

Huidige zorgverlening

Er werd een survey uitgevoerd naar de huidige praktijk betreffende ontwikkelingsgerichte zorg. NICU's in Nederland en Vlaanderen werden onderzocht met behulp van een vragenlijst. Deze lijst bevatte vijf domeinen: Zorgprincipes, Conceptbeschrijving, Faciliteiten en Hulpmiddelen, Medewerkers en Deskundigheid, Onderzoek en Toekomst. Er bleek consensus te bestaan over de definitie van ontwikkelingsgerichte zorg, maar zowel de invulling van het concept als de beschikbaarheid van mogelijkheden en materialen lieten grote diversiteit zien. Sommige NICU's beschikten over professionals met een hoog expertise niveau en specifieke training (NIDCAP gecertificeerd).

In de onderzochte NICU's bleek een continuüm van ontwikkelingsgerichte zorg te bestaan. Aan de ene kant van dit continuüm staan de ontwikkelingsgerichte zorg initiatieven van individuele zorgverleners. Aan de andere kant staat de ontwikkelingsgerichte zorg op basis van NIDCAP principes, gekarakteriseerd door geïndividualiseerde zorg op basis van gedragsobservaties en de beschikbaarheid van kennis en kunde. Daar tussenin staat de ontwikkelingsgerichte zorg met beschikbaarheid van materialen en middelen, management steun en een ontwikkelingsgericht afdelingsbeleid.

Implementatie

De implementatie van NIDCAP startte met de training en certificering tot NIDCAP observatoren van vijf verpleegkundigen. De gehele verpleegkundige en medische staf kregen scholing in de theoretische principes en praktische vaardigheden, nodig om NIDCAP te kunnen toepassen. Ouders, verpleegkundigen en artsen werden gecoacht in het toepassen van de aanbevelingen, voortkomend uit de gedragsobservatie, de aanpassing van omgeving en zorg en de individuele interventies, door de gecertificeerde verpleegkundigen. De observaties startten binnen drie dagen na geboorte en werden iedere zeven tot tien dagen of bij grote veranderingen herhaald. NIDCAP zorg werd beëindigd bij ontslag van de NICU.

Wij bestudeerden de korte termijn klinische uitkomsten, ontwikkeling en groei, ouder- en werktevredenheid voor en na implementatie van NIDCAP. Kinderen geboren met een zwangerschapsduur van minder dan 30 weken werden daartoe geïncludeerd in een prospectief gefaseerde (phase-lag) cohort studie.

De studiegroep bestond uit 26 pasgeborenen in de conventionele groep en 26 pasgeborenen in de NIDCAP groep. Bij opname in de studie hadden de pasgeborenen uit de NIDCAP groep een significant lager geboortegewicht, waren vaker te licht van gewicht voor de zwangerschapsduur, hadden een kleinere schedelomtrek en vergeleken

bij de pasgeborenen van de conventionele groep was er minder vaak sprake van een tweeling. Tijdens het verblijf van de pasgeborenen uit de NIDCAP groep op de NICU deed zich tweemaal een nosocomiale infectie uitbraak voor. Hierdoor ontwikkelden, statistisch significant meer, pasgeborenen uit de NIDCAP groep een pneumonie.

Klinische uitkomsten

Na corrigeren voor bovenstaande groepsverschillen werd een statistisch significant verminderd risico op ernstige cerebrale schade gezien in het voordeel van de NIDCAP groep. Er werden geen verschillen gezien in de respiratoire status, de groei tijdens het verblijf op de NICU en de duur van het verblijf op de NICU.

Ontwikkelingsuitkomsten

We zagen geen effect van NIDCAP op de mentale of psychomotore ontwikkelingsuitkomsten van overlevende pasgeborenen. Na correctie voor groepsverschillen en bekende voorspellers van ontwikkelingsuitkomsten zagen we geen verschil tussen beide zorggroepen. Op de à terme leeftijd waren pasgeborenen uit de NIDCAP groep autonoom en motorisch minder stabiel vergeleken met de pasgeborenen uit de conventionele groep. Er werden geen verschillen gezien in de neurologische status of in de groei parameters gedurende de eerste 24 maanden.

Ouder tevredenheid

Tevredenheid van ouders werd vastgesteld door middel van twee vragenlijsten. Een voor de gehele zorg op de NICU en de ander voor de mate van ondersteuning door de verpleegkundigen. Ouders waren statistisch significant meer tevreden met de zorg volgens de NIDCAP principes dan de conventionele zorg voor hun prematuur geboren kind. De vermeende mate van ondersteuning door de verpleegkundigen was hoger voor de ouders van de NIDCAP groep maar niet statistisch significant.

Werktevredenheid

Om het effect van het implementeren van NIDCAP op de werktevredenheid van de verpleegkundige staf vast te stellen, werd een pre- en post-survey uitgevoerd onder gediplomeerde verpleegkundigen met een Intensive Care Neonatologie diploma of daarvoor in opleiding. Er werden geen verschillen gezien in de achtergrond kenmerken tussen deelnemers van de pre- en post-survey groep. De belangrijkheid van de individuele componenten van werktevredenheid werd voor en na het introduceren van NIDCAP op gelijke wijze gerangschikt. Tevredenheid over de individuele componenten werd eveneens voor en na NIDCAP introductie op gelijke wijze gerangschikt. De index van werktevredenheid was bij de post-survey iets toegenomen in vergelijking met de pre-survey.

De scores suggereren dat de verpleegkundige staf bij herhaling tevreden is over hun werk. Grote veranderingen in de verpleegkundige zorg, door het introduceren van NIDCAP op de NICU, hebben nauwelijks invloed gehad op de algehele werktevredenheid.

Methodologische kwesties

De huidige studies betreffen kleine steekproeven en niet gerandomiseerde vergelijkingen. NIDCAP kan gezien worden als een complexe interventie, bestaande uit diverse onderdelen die onderling verbonden zijn en die zich zowel onafhankelijk als afhankelijk van elkaar voordoen, die om een andere methode van evaluatie van effecten vraagt. Deze interventie vraagt om een andere methode van evaluatie van effecten.

Standaardisatie van uitkomst parameters, meetmethoden en consistentie van het tijdstip van meten is nodig om resultaten van separate studies te kunnen vergelijken en het punt van niet randomiseren en kleine steekproeven zoals in onze studies te overkomen.

Onze studies werden belemmerd door een andere methodologische kwestie; NIDCAP en conventionele groepen waren, met betrekking tot zowel de achtergrond kenmerken als sommige klinische kenmerken, niet gelijk. Echter voor deze verschillen werd gecorrigeerd met behulp van een multivariaat analysemodel.

Tenslotte werden we beperkt in het vergelijken van onze resultaten met die van andere studies doordat de NIDCAP interventieduur beperkt was tot de NICU periode. In Nederland worden pasgeborenen overgeplaatst naar regionale ziekenhuizen zodra intensieve zorg niet langer is vereist. Ten tijde van de studie was ontwikkelingsgerichte zorg in de regionale ziekenhuizen geen gemeengoed.

Integratie van resultaten van de studies in dit proefschrift, gecombineerd met de methodologische kwesties, resulteren in de volgende implicaties voor verder onderzoek en de klinische praktijk.

Implicaties voor onderzoek

Onderzoek naar stress zou zich moeten richten op meting, preventie en behandeling ervan. Het zou een grote stap voorwaarts zijn als er consensus zou bestaan over het gebruik van de Comfort schaal als het instrument om stress bij premature pasgeborenen te meten. Studies naar adequaat gebruik van analgetica en sedativa is nodig.

Het uitvoeren van een multi-center NIDCAP studie waarbij naast kwantitatieve en kwalitatieve methoden, gezichtspunten vanuit de medische, verpleegkundige en gedragswetenschappen gecombineerd worden, zou waardevol zijn en wordt aanbevolen. Naast medische uitkomsten zou de evaluatie zich moeten richten op het vaststellen van psychologische en morfologische veranderingen in de functie van de hersenen, op welzijn en gedrag van de pasgeborenen, op welzijn van de ouders en op de tevredenheid van professionals.

Het bestuderen van NIDCAP zou zich ook moeten richten op het reactiepatroon van premature pasgeborenen die uitgedaagd of geprikkeld worden. Is het gedrag

van pasgeborenen, verzorgd volgens NIDCAP, meer georganiseerd, laten zij minder stressgedrag zien en hoe is hun (zelf)regulatie vergeleken met conventioneel verzorgde pasgeborenen.

Een ander aspect van studie is de wenselijke duur van de interventie, de continuïteit van geïndividualiseerde ontwikkelingsgerichte zorg, zowel gedurende het verblijf op de NICU alsook in het daaropvolgende verblijf in het regionale ziekenhuis.

De culturele context en overtuiging in relatie tot ontwikkelingsgerichte zorg en NIDCAP is een vraag die beantwoord moet worden in toekomstig onderzoek.

De economische impact van de implementatie en het onderhoud van de ontwikkelingsgerichte zorg praktijk moeten geëvalueerd worden. Kostenbesparing, tengevolge van verminderde medische consumptie door premature pasgeborenen, moet onderzocht worden om te weten of we in tijden van beperkte financiële mogelijkheden daadwerkelijk moeten investeren in NIDCAP.

Implicaties voor de klinische praktijk

Een ontwikkelingsgerichte zorg omgeving voor pasgeborenen en hun ouders, in combinatie met geïndividualiseerde ontwikkelingsgerichte zorg op basis van regelmatige observaties van gedrag volgens de NIDCAP, zou geïntegreerd moeten worden in de klinische praktijk van de NICU.

Alle potentiële pijnlijke of stressvolle perioden en gebeurtenissen zouden gemeten moeten worden met de Comfort schaal en acties om stress, pijn en discomfort te voorkomen zouden vastgelegd moeten worden in een individueel zorgplan.

Het is aan te bevelen dat ontwikkelingsgerichte zorg en NIDCAP multidisciplinair worden geïmplementeerd omdat het alle bij de zorg van premature pasgeborenen betrokken disciplines betreft. Tijdens de daadwerkelijke implementatie moet de verpleegkundige discipline, als ruggengraat van de NICU, een speciale plaats innemen. Het is ook aanbevelenswaardig om gebruik te maken van de beschikbare expertise en kennis van NICU's die de ontwikkelingsgerichte zorg en NIDCAP al geïmplementeerd hebben.

Conclusies

Ondanks de methodologie kwesties en beperkte bewijzen van medische en ontwikkelings-uitkomsten zijn de resultaten van dit proefschrift bemoedigend. NIDCAP werd goed ontvangen door ouders maar ook door de verpleegkundige staf. Het is een attractief concept vanuit menselijk perspectief. Ondanks de behoefte aan verder onderzoek is het redelijk om de NICU's aan te moedigen ontwikkelingsgerichte zorg te implementeren. Ontwikkelingsgerichte zorg minstens bestaande uit individuele gedragsobservaties en het vaststellen van stress en discomfort om routines en structuren die de gezondheidstoestand, het welzijn en de neurologische ontwikkeling van de pasgeborenen en het welzijn van ouders ondermijnen te voorkomen en de pasgeborenen te steunen zich zo optimaal mogelijk te kunnen ontwikkelen.

Appendices

Index of Work Satisfaction
NICU- Parent Satisfaction Form
NIDCAP® Naturalistic Observation of Newborn Behavior
Nurse Parent Support Tool

Appendix A -The Index of Work Satisfaction Questionnaire ©

Part A (Paired Comparisons)

Listed and briefly defined below are six terms or factors that are involved in how people feel about their work situation. Each factor has something to do with "work satisfaction". We are interested in determining which of these is most important to you in relation to the others.

Please carefully read the definitions for each factor as given below:

- **Pay** -- dollar remuneration and fringe benefits received for work done
- **Autonomy** -- amount of job related independence, initiative, and freedom, either permitted or required in daily work activities.
- **Task Requirements** -- tasks or activities that must be done as a regular part of the job
- **Organizational Policies** -- management policies and procedures put forward by the hospital and nursing administration of this hospital
- **Interaction** -- opportunities presented for both formal and informal social and professional contact during working hours
- **Professional Status** -- overall importance or significance felt about your job, both in your view and in the view of others

Instructions: These factors are presented in pairs on the next page. A total of 15 pairs are presented: this is every set of combinations. No pair is repeated or reversed. For each pair of terms, decide which one is more important for your job satisfaction or morale, and check the appropriate box. For example, if you feel that Pay (as defined above) is more important than Autonomy (as defined above), check the box for Pay.

It will be difficult for you to make choices in some cases. However, please do try to select the factor which is more important to you. Please make an effort to answer every item; do not go back to change any of your answers.

Part A (Paired Comparisons, Continued)

Please choose the one member of the pair which is most important to you.

1.	☐ Professional Status	or	☐ Organizational Policies
2.	☐ Pay Requirements	or	☐ Task Requirements
3.	☐ Organizational Policies	or	☐ Interaction
4.	☐ Task Requirements	or	☐ Organizational Policies
5.	☐ Professional Status	or	☐ Task Requirements
6.	☐ Pay	or	☐ Autonomy
7.	☐ Professional Status	or	☐ Interaction
8.	☐ Professional Status	or	☐ Autonomy
9.	☐ Interaction	or	☐ Task Requirements
10.	☐ Interaction	or	☐ Pay
11.	☐ Autonomy	or	☐ Task Requirements
12.	☐ Organizational Policies	or	☐ Autonomy
13.	☐ Pay	or	☐ Professional Status
14.	☐ Interaction	or	☐ Autonomy
15.	☐ Organizational Policies	or	☐ Pay

Part B (Attitude Questionnaire)

The following items represent statements about how satisfied you are with your current nursing job. Please respond to each item. It may be very difficult to fit your responses into the seven categories; in that case, select the category that comes closest to your response to the statement. It is very important that you give your honest opinion. Please do not go back and change any of your answers.

Instructions: Please circle the number that most closely indicates how you feel about each statement. The left set of numbers indicates degrees of agreement. The right set of numbers indicates degrees of disagreement. For example, if you strongly agree with the first item, circle 1; if you agree with this item, circle 2; if you moderately agree with the first statement, circle 3. The middle response (4) is reserved for feeling neutral or undecided. Please use it as little as possible. If you moderately disagree with this first item, you should circle 5; to disagree, circle 6; and to strongly disagree, circle 7.

Part B (Attitude Questionnaire, Continued)

Remember: The more strongly you feel about the statement, the further from the center you should circle, with agreement to the left and disagreement to the right. Use 4 for neutral or undecided if needed, but please try to use this number as little as possible.

		Agree						Disagree
1.	My present salary is satisfactory.	1	2	3	4	5	6	7
2.	Nursing is not widely recognized as being an important profession.	1	2	3	4	5	6	7
3.	The nursing personnel on my service pitch in and help one another out when things get in a rush.	1	2	3	4	5	6	7
4.	There is too much clerical and "paperwork" required of nursing personnel in this hospital.	1	2	3	4	5	6	7
5.	The nursing staff has sufficient control over scheduling their own shifts in my hospital.	1	2	3	4	5	6	7
6.	Physicians in general cooperate with nursing staff on my unit.	1	2	3	4	5	6	7
7.	I feel that I am supervised more closely than is necessary.	1	2	3	4	5	6	7
8.	It is my impression that a lot of nursing personnel at this hospital are dissatisfied with their pay.	1	2	3	4	5	6	7
9.	Most people appreciate the importance of nursing care to hospital patients.	1	2	3	4	5	6	7
10.	It is hard for new nurses to feel 'at home' in my unit.	1	2	3	4	5	6	7
11.	There is no doubt whatever in my mind that what I do on my job is really important.	1	2	3	4	5	6	7
12.	There is a great gap between the administration of this hospital and the daily problems of the nursing service.	1	2	3	4	5	6	7
13.	I feel I have sufficient input into the program of care for each of my patients.	1	2	3	4	5	6	7
14.	Considering what is expected of nursing service personnel at this hospital, the pay we get is reasonable.	1	2	3	4	5	6	7
15.	I think I could do a better job if I did not have so much to do all the time.	1	2	3	4	5	6	7
16.	There is a good deal of teamwork and cooperation between various levels of nursing personnel on my service.	1	2	3	4	5	6	7

Part B (Attitude Questionnaire, Continued)

Remember: The more strongly you feel about the statement, the further from the center you should circle, with agreement to the left and disagreement to the right. Use 4 for neutral or undecided if needed, but please try to use this number as little as possible.

		Agree						Disagree
17.	I have too much responsibility and not enough authority.	1	2	3	4	5	6	7
18.	There are not enough opportunities for advancement of nursing personnel at this hospital.	1	2	3	4	5	6	7
19.	There is a lot of teamwork between nurses and doctors on my own unit.	1	2	3	4	5	6	7
20.	On my service, my supervisors make all the decisions. I have little direct control over my own work.	1	2	3	4	5	6	7
21.	The present rate of increase in pay for nursing service personnel at this hospital is not satisfactory.	1	2	3	4	5	6	7
22.	I am satisfied with the types of activities that I do on my job.	1	2	3	4	5	6	7
23.	The nursing personnel on my service are not as friendly and outgoing as I would like.	1	2	3	4	5	6	7
24.	I have plenty of time and opportunity to discuss patient care problems with other nursing service personnel.	1	2	3	4	5	6	7
25.	There is ample opportunity for nursing staff to participate in the administrative decision-making process.	1	2	3	4	5	6	7
26.	A great deal of independence is permitted, if not required, of me.	1	2	3	4	5	6	7
27.	What I do on my job does not add up to anything really significant.	1	2	3	4	5	6	7
28.	There is a lot of "rank consciousness" on my unit: nurses seldom mingle with those with less experience or different types of educational preparation.	1	2	3	4	5	6	7
29.	I have sufficient time for direct patient care.	1	2	3	4	5	6	7
30.	I am sometimes frustrated because all of my activities seem programmed for me.	1	2	3	4	5	6	7
31.	I am sometimes required to do things on my job that are against my better professional nursing judgment.	1	2	3	4	5	6	7

Part B (Attitude Questionnaire, Continued)

Remember: The more strongly you feel about the statement, the further from the center you should circle, with agreement to the left and disagreement to the right. Use 4 for neutral or undecided if needed, but please try to use this number as little as possible.

		Agree						Disagree
32.	From what I hear about nursing service personnel at other hospitals, we at this hospital are being fairly paid.	1	2	3	4	5	6	7
33.	Administrative decisions at this hospital interfere too much with patient care.	1	2	3	4	5	6	7
34.	It makes me proud to talk to other people about what I do on my job.	1	2	3	4	5	6	7
35.	I wish the physicians here would show more respect for the skill and knowledge of the nursing staff.	1	2	3	4	5	6	7
36.	I could deliver much better care if I had more time with each patient.	1	2	3	4	5	6	7
37.	Physicians at this hospital generally understand and appreciate what the nursing staff does.	1	2	3	4	5	6	7
38.	If I had the decision to make all over again, I would still go into nursing.	1	2	3	4	5	6	7
39.	The physicians at this hospital look down too much on the nursing staff.	1	2	3	4	5	6	7
40.	I have all the voice in planning policies and procedures for this hospital and my unit that I want	1	2	3	4	5	6	7
41.	My particular job really doesn't require much skill or "know-how".	1	2	3	4	5	6	7
42.	The nursing administrators generally consult with the staff on daily problems and procedures.	1	2	3	4	5	6	7
43.	I have the freedom in my work to make important decisions as I see fit, and can count on my supervisors to back me up.	1	2	3	4	5	6	7
44.	An upgrading of pay schedules for nursing personnel is needed at this hospital.	1	2	3	4	5	6	7

Appendix B -Neonatal Intensive Care Unit Parent Satisfaction Form (NICU-PSF)

Instructions: This questionnaire asks your opinion on the care that your baby received during the stay at the NICU. This information will help us improve family care.

Answer each question by marking the answer. When you are in doubt how to answer the question, answer as well as you can.

OVERALL RATING

1. In general, how satisfied were you with your baby's...

A. Overall care (mark only one answer)	
Not at all satisfied	1
Slightly satisfied	2
Moderately satisfied	3
Quite satisfied	4
Extremely satisfied	5
B. Medical care	
Not at all satisfied	1
Slightly satisfied	2
Moderately satisfied	3
Quite satisfied	4
Extremely satisfied	5
C. Nursing care	
Not at all satisfied	1
Slightly satisfied	2
Moderately satisfied	3
Quite satisfied	4
Extremely satisfied	5

2. In general, how do you score your baby's...

A. Hospital stay	
Poor	1
Moderate	2
Good	3
Very Good	4
Excellent	5
B. Medical care	
Poor	1
Moderate	2
Good	3
Very Good	4
Excellent	5

C. Nursing care

Poor	1
Moderate	2
Good	3
Very Good	4
Excellent	5

YOUR BABY'S CARE

3. Who was mostly responsible for the daily care of your baby?

Pediatrician/Neonatologist	1

4. How well do you think did the neonatologist manage to stick to the careplan of your baby?

Poor	1
Moderate	2
Good	3
Very Good	4
Excellent	5

5. How well do you think did the pediatric resident manage to stick to the careplan of your baby?

Poor	1
Moderate	2
Good	3
Very Good	4
Excellent	5

6. How well do you think did the nurse manage to stick to the careplan of your baby?

Poor	1
Moderate	2
Good	3
Very Good	4
Excellent	5

7. How much of the time did you consider that the given care to your baby was consistent or smooth?

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

8. How often was the careplan of your baby adapted due to a change in nursing or medical staff and not due to the condition of your baby?

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

COMMUNICATION WITH STAFF

9. How often did the medical staff (pediatricians, residents) explain problems to you in a way you understood?

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

10. The medical staff (pediatricians, residents) listened carefully to me.

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

11. The medical staff (pediatricians, residents) understood how I felt.

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

12. How often did the nursing staff explain medical problems to you in a way you understood?

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

13. The nursing staff listened carefully to me.

None of the time	1
A little of the time	2
Some of the time	3

Most of the time	4
All of the time	5

14. The nursing staff understood how I felt?

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

15. In general, what is your opinion on the communication between you and the....

A. Pediatrician/neonatologist

Poor	1
Moderate	2
Good	3
Very good	4
Excellent	5

B. Pediatric Resident

Poor	1
Moderate	2
Good	3
Very good	4
Excellent	5

C. Nursing staff

Poor	1
Moderate	2
Good	3
Very good	4
Excellent	5

16. How would you describe the amount of time talking with the...

A. Pediatrician/neonatologist

Not nearly enough	1
Less than enough	2
Almost enough	3
Enough	4

B. Pediatric Resident

Not nearly enough	1

Less than enough	2
Almost enough	3
Enough	4

C. Nursing staff

Not nearly enough	1
Less than enough	2
Almost enough	3
Enough	4

INVOLVEMENT IN CARE

17. Did the medical staff ask you to choose medical treatments for your baby?

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

18. Did you want to be involved in the decision making concerning the medical treatment for your baby?

medical treatment for your baby?	
None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

19. How would you describe your involvement in planning your baby's care?

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

20. How would you describe the amount of time the nurses spent teaching you how to take care of your baby?

Poor	1
Moderate	2
Good	3
Very Good	4
Excellent	5

21. How would you describe the way nurses taught you how to take care of your baby?

Poor	1
Moderate	2
Good	3
Very Good	4
Excellent	5

22. How would you describe the amount of support or encouragement that you received from the nurses in taking care of your baby?

Poor	1
Moderate	2
Good	3
Very Good	4
Excellent	5

BEING PREPARED

23. How often did the medical staff (pediatricians, residents) prepare you for potential problems your baby may have?

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

24. How often did the nursing staff prepare you for potential problems your baby may have?

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

26. When events happened to your baby, how often did you feel prepared enough to be able to deal with them?

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

27. Did you find it helpful to be prepared for problems that might occur?

Not at all helpful	1

A little helpful	2
Somewhat helpful	3
Very helpful	4

28. How prepared were you to take care for your baby when the time came to take your baby home?

Not nearly prepared	1
Less than prepared	2
Almost prepared	3
Prepared	4
Not relevant	0

29. After being home for a time, how prepared were you to care for your baby at home?

Not nearly prepared	1
Less than prepared	2
Almost prepared	3
Prepared	4
Doesn't apply to me	0

SUPPORT

30. How much of the time did you feel supported by the....

A. Medical staff (pediatrician, residents)

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

B. Nursing staff

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

C. Hospital Social worker

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

D. Hospital Clergymen (pastor, priest etc.)

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

30. Were you able to ask for help when you needed it?

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

31. How often did you receive the help you needed and asked for?

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

32. Did you have spiritual or religious needs during the stay of your baby in the hospital?

No	1
Yes	2

33. Were your spiritual or religious beliefs supported during the stay of your baby in the hospital?

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5
Doesn't apply to me	0

34. Were your spiritual or religious needs met during the stay of your baby in the hospital?

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4

All of the time	5
Doesn't apply to me	0

BEING A PARENT

35. How much of the time did you have the feeling that your baby was not yours during the hospital stay of your baby?

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

36. How much of the time did you feel like a parent when your baby was hospitalized?

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

37. How much of the time did the NICU staff encourage you to be a parent to your baby?

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

BEING NEAR YOUR BABY

38. Did the hospital offer you a nearby place to stay while your baby was hospitalized?

No	1
Yes	2

39. How much of the time did you want to spend with your baby while your baby was hospitalized?

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

40. How much of the time were you encouraged to be with your baby during your baby's stay in the hospital?

None of the time	1

A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

41. How much of the time were you free to go into the intensive care to spend time with your baby?

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

42. How much of the time were your family members free to go into the intensive care to spend time with your baby?

None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

43. How satisfied were you with the family visiting policy of the intensive care?

Not at all satisfied	1
Slightly satisfied	2
Moderately satisfied	3
Quite satisfied	4
Extremely satisfied	5

FOLLOW – UP CARE

44. Did your baby receive follow up care?

No	1
Yes	2

45. Which type of specialized follow up care did your baby receive?

Neonatology	1
Cardiology	2
Neurology	3
Opthalmology	4
Fysiotherapist	5
Surgical	6
Others	7

Does not apply	8

46. How would you rate your baby's follow up care?

Poor	1
Moderate	2
Good	3
Very Good	4
Excellent	5

ABOUT YOU

47. Are you male or female?

Male	1
Female	2

48. Are you ...

Married /living together in common law	1
Divorced	2
Single	3

49. Are you the baby's....

Mother	1
Father	2
Grandmother	3
Grandfather	4
Other	5

50. How old were you on your last birthday?

Under 18	1
18-24 years of age	2
25-34 years of age	3
35-44 years of age	4
45+ years of age	5

51. How would you describe the race of your baby?

Caucasian	1
African	2
Asian	3
Multiracial	4
Other	5

SURPRISES AND DISAPPOINTMENTS

52. What positive surprises did you receive while your baby was in the hospital?

53. What disappointments did you experience while your baby was in the hospital?

54. What suggestions do you have to help us improve the care for you as well as your baby ?

55. Do you have any remarks to add concerning the care of your baby or the hospital stay ?

56. Would you recommend this hospital for medical care?

No	1
Yes	2

Thank you for filling out this questionnaire!

Appendix C -NIDCAP® Naturalistic Observation of Newborn Behavior

OBSERVATION SHEET Name:_____ Date:_____ Sheet Number_____

		Time:	0-2	3-4	5-6	7-8	9-10
Resp:	Regular						
	Irregular						
	Slow						
	Fast						
	Pause						
Color:	Jaundice						
	Pink						
	Pale						
	Webb						
	Red						
	Dusky						
	Blue						
	Tremor						
	Startle						
	Twitch Face						
	Twitch Body						
	Twitch Extremities						
Visceral/ Resp:	Spit up						
	Gag						
	Burp						
	Hiccough						
	BM Grunt						
	Sounds						
	Sigh						
	Gasp						
Motor:	Flaccid Arm(s)						
	Flaccid leg(s)						
	Flexed/ Tucked Arms	Act.					
		Post.					
	Flexed/ Tucked Legs	Act.					
		Post.					
	Extend Arms	Act.					
		Post.					
	Extend Legs	Act.					
		Post.					
	Smooth Mvmt Arms						
	Smooth Mvmt Legs						
	Smooth Mvmt Trunk						
	Stretch/Drown						
	Diffuse Squirm						
	Arch						
	Tuck Trunk						
	Leg Brace						
Face:	Tongue Extension						
	Hand on Face						
	Gape Face						
	Grimace						
	Smile						

		Time:	0-2	3-4	5-6	7-8	9-10
State:	1A						
	1B						
	2A						
	2B						
	3A						
	3B						
	4A						
	4B						
	5A						
	5B						
	6A						
	6B						
	AA						
Face (cont.):	Mouthing						
	Suck Search						
	Sucking						
Extrem.:	Finger Splay						
	Airplane						
	Salute						
	Sitting On Air						
	Hand Clasp						
	Foot Clasp						
	Hand to Mouth						
	Grasping						
	Holding On						
	Fisting						
Attention:	Fuss						
	Yawn						
	Sneeze						
	Face Open						
	Eye Floating						
	Avert						
	Frown						
	Ooh Face						
	Locking						
	Cooing						
	Speech Mvmt.						
Posture:	(Prone, Supine, Side)						
Head:	(Right, Left, Middle)						
Location:	(Crib, Isolette, Held)						
Manipulation:							
	Heart Rate						
	Respiration Rate						
	$TcPO_2$						

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Appendix D -The Nurse Parent Support Tool

We are interested in your opinion on how the nursing staff who took care of your child attended to your needs or supported you during the stay of your child on our ward.
Please answer all the underlying questions by encircling the answer that comes closest to the way nurses helped you.

THE NURSING STAFF OF THE NEONATAL INTENSIVE CARE UNIT OF THE AMC IN GENERAL:

1. Helped me to express my feelings, needs and concerns at the time.
   hardly ever not very often some of the time often almost always

2. Helped me understand what was happening to my child (for example during procedures, treatment, medication, etc.).
   hardly ever not very often some of the time often almost always

3. Taught me how to take care of my child.
   hardly ever not very often some of the time often almost always

4. Saw to it that I felt important being a parent.
   hardly ever not very often some of the time often almost always

5. Gave me the choice to stay or leave during medical procedures.
   hardly ever not very often some of the time often almost always

6. Answered my questions satisfactorily or saw to it that someone could provide the answer.
   hardly ever not very often some of the time often almost always

7. Informed me about the changes / improvements concerning the condition of my child.
   hardly ever not very often some of the time often almost always

8. Involved me in discussions on decisions that had to be made concerning the care of my child.
   hardly ever not very often some of the time often almost always

9. Helped me understand the behavior and reactions of my child.
   hardly ever not very often some of the time often almost always

10. Explained to me how I could comfort my child during and after procedures.
    hardly ever not very often some of the time often almost always

11. Let me know I am doing well in supporting my child.
    hardly ever not very often some of the time often almost always

12. Responded to my worries and concerns.
    hardly ever not very often some of the time often almost always

13. Showed interest in my well being (for example sleeping, eating, etc).
    hardly ever not very often some of the time often almost always

14. Told me the names and qualifications of those who took care of my child
    hardly ever not very often some of the time often almost always

15. Gave good care to my child.
    hardly ever not very often some of the time often almost always

16. Encouraged me to ask questions about my child.
    hardly ever not very often some of the time often almost always

17. Showed sensitivity to the special needs of my child.
    hardly ever not very often some of the time often almost always

18. Allowed me to be involved in the care of my child, whenever possible.
    hardly ever not very often some of the time often almost always

19. Showed that they like my child.
    hardly ever not very often some of the time often almost always

20. Reacted towards the needs of my child within reasonable time.
    hardly ever not very often some of the time often almost always

21. Expressed optimism about my child.
    hardly ever not very often some of the time often almost always

If there are any other things that the nurses did that helped you as a parent please add them here:

Are there other things the nurses could have done to support you as a parent?
If so, please add them here:

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Curriculum Vitae

Joke Wielenga werd in 1959 in Amsterdam geboren. Na de HAVO aan het Cartesius Lyceum / Reina Prinsen Geerligs HAVO in haar woonplaats te hebben doorlopen, begon zij in 1977 haar HBO-Verpleegkunde opleiding in Amstelveen. In 1981 ronde zij deze opleiding af en begon haar verpleegkundige carrière in het toenmalige Burgerziekenhuis te Amsterdam. In 1982 maakte zij de overstap naar het toenmalige Wilhelmina Gasthuis te Amsterdam, om aldaar de verpleegkundige specialistische opleiding Obstetrie & Gynaecologie te volgen. Na het doorlopen van deze opleiding startte zij in 1983 de verpleegkundige specialistische opleiding tot neonatologie verpleegkundige. Vanaf 1983 is zij werkzaam op de afdeling IC neonatologie van het Emma Kinderziekenhuis / Academisch Medisch Centrum te Amsterdam. In 1990 startte zij met haar studie Gezondheidswetenschappen aan de Rijks Universiteit Limburg (tegenwoordig Universiteit Maastricht) te Maastricht. Haar afstudeerproject voor de richting Verplegingswetenschappen, betrof onderzoek naar gebruikte indicatoren ter vaststelling van pijn bij pasgeborenen door IC Neonatologie verpleegkundigen. Haar begeleider was Prof. Dr. Huda Huyer – Abu Saad. Haar doctoraal examen behaalde zij in 1995. In 1996/97 volgde zij de opleiding Klinische Epidemiologie voor Verpleegkundigen waarvoor zij onderzoek deed naar de Comfort Schaal en stress bij de pasgeborenen (zie hoofdstuk 2 en 3 van dit proefschrift). Sinds 1996 combineert zij haar werk als verpleegkundige IC Neonatologie met dat van verpleegkundig onderzoeker. Sinds 2003 is zij wetenschappelijk onderzoeker op de afdeling IC Neonatologie. In 1999 werd zij in Boston door Prof. Dr. Heidelise Als getraind in het uitvoeren van Naturalistic Behavioral Observation binnen het Newborn Individualized Developmental Care and Assessement Program (NIDCAP). Certificatie volgde in 2001 in Zweden door Dr. Agneta Kleberg.

Joke Wielenga heeft een zoon, Thijs, samen wonen zij in Amsterdam.