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The effect of in-hospital developmental care on neonatal morbidity, growth and development of preterm Taiwanese infants: A randomized controlled trial☆

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ABSTRACT

Introduction: Intervention studies of developmental care for preterm infants in Western societies have shown early but unsustainable effects on child outcomes, however only a limited of studies have examined if developmental care interventions produce similar effects in Eastern cultural contexts.
Aims: To examine the effectiveness of in-hospital developmental care on neonatal morbidity, growth and development of preterm infants with very low birth weight (VLBW; birth weight<1500 g) in Taiwan.
Methods: One hundred and seventy-eight VLBW preterm infants were randomly assigned to the clinical trial during hospitalization at three hospitals in Taiwan; the control group received five sessions of standard child-focused developmental care and the intervention group received five sessions of child- and parent-focused developmental care. Sixty-two normal term infants were also included as a comparison group. Infants were examined for morbidity, growth and developmental outcomes at term age.
Results: At study entry, more infants in the intervention group were twins or multiples than those in the control group (29% vs. 16%, $p=0.05$). After adjusting for birth set, the intervention group had lower incidences of stage II–III retinopathy (odds ratio [OR]=0.34 [95% confidence interval (CI): 0.15–0.79]; $p=0.01$) and feeding desaturation (OR=0.32 [95% CI: 0.10–1.00]; $p=0.05$) and had greater daily weight gains (difference=2.0 g/day [95% CI: 0–4.0 g/day]; $p=0.05$) as compared with the control group. However, the intervention and control groups did not differ in any of the neurodevelopmental measures.
Conclusions: In-hospital developmental care has short-term benefits for Taiwanese VLBW preterm infants in reducing the risk of retinopathy and feeding desaturation as well as in enhancing weight gains at term age.

1. Introduction

Preterm infants with very low birth weight (VLBW; birth weight<1500 g) enter this world with disadvantages and face many developmental challenges when they are most fragile. One of these challenges is that they actually are fetuses developing in extra-uterine settings at a time when their brains are growing more rapidly than at any other time in their life [1]. Approximately 40% of VLBW preterm infants is susceptible to unfavorable outcomes, ranging from chronic health problems and re-hospitalizations to developmental delays when compared with term infants with normal birth weight at early ages [2]. Their developmental difficulties, such as lower intelligence quotients, behavioral problems and academic performance limitations, may even persist into school age [3]. Considering the implications of preterm birth problems and their costs to medical, family and educational systems, efforts are needed for developing effective interventions to enhance the outcomes in VLBW preterm infants.

Early intervention of developmental care for preterm infants may be broadly divided into two types: in-hospital and after-discharge interventions [4]. Meta-analyses have shown that in-hospital developmental cares have a significant effect on reducing the requirement for supplemental oxygen and the incidence of bronchopulmonary dysplasia (BPD) and necrotizing enterocolitis (NEC) and improving

☆ This trial was registered at clinicaltrials.gov as NCT00173108.

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neurodevelopment until twelve months of age [5,6]. Regarding after-discharge developmental cares, a large body of literature indicates that their effects on child development are small to moderate at early ages, with differences waning by five years of age [7]. Further analysis of program characteristics revealed that comprehensive interventions starting early after discharge and combining child- and parent-focused services were most likely to be effective [4]. These reviews appear to indicate that developmental care before term may have some early but unsustainable effect on child outcomes.

Despite the abundant insights gained from previous developmental care studies with preterm infants, several important issues remain inadequately addressed. First, the limited evidence of supporting the effectiveness of some developmental care studies might be due to non-randomized designs, small sample sizes, heterogeneity of the samples, and/or flaws in methodologies. Rigorous clinical trials with sufficient sample sizes are needed to better understand the effectiveness of early developmental care. Second, most of the prior intervention studies were conducted in Western societies and the only study conducted in Asia was restricted to after-discharge developmental care [8]. Because there are substantial variations in health care systems and parental beliefs between societies, investigation into whether developmental care interventions produce similar effects in different cultural contexts is necessary.

Current developmental care for preterm infants in Taiwan is limited to child-focused services in NICUs and neonatal clinic visits after discharge for the continuation of medical care. To fill the gap, our research team has developed comprehensive interventions that combine child- and parent-focused services for VLBW preterm infants. This program includes 13-session developmental cares that begins in the hospital and ends at 12 months of corrected age. After hospital discharge, VLBW infants in the intervention group were further separated into a clinic- and a home-based group as part of the follow-up study. Focusing on the short-term effect at term age, the present study examined the effectiveness of our comprehensive in-hospital interventions relative to the standard developmental care in a large sample of VLBW preterm Taiwanese infants. Using a multi-site, randomized controlled trial, the short-term effectiveness was assessed by the morbidity, growth and developmental outcomes at term age. A normal birth weight term reference group was also included to help determine if developmental cares successfully offset the risk associated with preterm birth.

2. Methods

2.1. Participants

This study enrolled VLBW preterm infants from three participating sites: the National Taiwan University Hospital, Mackay Memorial Hospital and the Branch for Women and Children at Taipei City Hospital in Taiwan during the period of 2006 to 2008. The inclusion criteria for VLBW preterm infants were: [1] birth weight <1500 g; [2] gestational age <37 weeks; [3] admission to the hospital within the first seven days of life; [4] singleton birth or the first child in a set of twins or multiples; [5] physiologically stable, i.e., no ventilator use, absence of apnea, bradycardia, or desaturation with or without oxygen use at post-menstrual age (PMA) of 36 weeks; [6] hospital discharge prior to PMA of 44 weeks; and [7] absence of congenital anomalies or severe neonatal diseases (i.e., seizures, hydrocephalus, ventriculoperitoneal shunt, periventricular leukomalacia [PVL], grade III–IV intraventricular hemorrhage [IVH] [9], NEC with colostomy and stage IV–V retinopathy of prematurity [ROP]) [10]. A power calculation with the significance at the 5% level indicated that sample sizes of 19 and 34 in each group would be required to allow 80% probability of respectively detecting a five-point difference in the developmental score and a 30% difference in the incidence of BPD. To further account for the attrition rate in our follow-up study (20%), at least 43 preterm infants should be recruited for each group. Normal term infants born at the same hospitals were also included as a comparison group. The inclusion criteria for term infants were: [1] birth weight >2500 g; [2] gestation age within 38 to 42 weeks; [3] intrauterine growth status as appropriate for gestational age; and [4] absence of severe prenatal or perinatal complications. Written informed consent was obtained from parents following a complete explanation of the study. The study was approved by the ethics committees of the participating hospitals.

2.2. Procedure

This study employed a single blind, randomized experimental design in which infants were assigned to the usual care program (UCP), clinic-based intervention program (CBIP), or home-based intervention program (HBIP) after parents signed the informed consent. Stratification by gestational age (≤ 30 weeks vs. >30 weeks) was imposed a priori. Randomization was computer-generated, stratified according to gestational age and recruitment site. All infants received identical medical treatments and nursing care. The pediatricians making the decision for hospital discharge, the nurses delivering care and the staff assessing outcomes were blinded as to which group the children were in to avoid bias. Parents were informed of group allocation but were told not to discuss the intervention content with the pediatricians and nurses.

The control group (UCP) received standard developmental care during hospitalization and neonatal follow-up medical care post discharge. The design of standard developmental care was based on the Synactive theory [11], which emphasizes the minimization of adverse impacts of the NICU environment such as alteration of the environment, positioning, and clustered care and teaching parents of child developmental skills (handling and specific exercise routines). A booklet that contained information on general child development was also provided to parents.

The intervention groups (CBIP and HBIP) received in-hospital interventions, neonatal follow-ups, and after-discharge interventions. In addition to the Synactive theory [11], in-hospital developmental care was also guided by the concept of Family-Centered Care [12], which emphasizes the building of parent–professional partnerships to involve parents early in caregiving routines to promote child development and parent–child interaction. Specific care included modulation of the NICU and teaching of child developmental skills (same as the control group) plus feeding support (changing the feeding mode, nipple type, schedule, posture, pacing, stimulations, or a combination of any of these factors), massage (skin-to-skin contact with the trunk and extremities) and parent support and education (interpretation of the infant's behavioral cues and parenting skills) (Table 1). Though not the focus of this study, after-discharge interventions were delivered at the same time as those neonatal follow-up visits (program features described elsewhere). A booklet and a CD that contained information on age-appropriate intervention activities were also provided. Intervention services were provided by seven physical therapists, whereas the environmental modulation was performed by the primary nurses.

2.3. Outcome measures

Outcome measures included morbidity, growth and neurodevelopmental parameters that were obtained from either chart reviews or standardized assessments when infants approached term age. Because the CBIP and the HBIP groups received identical in-hospital services and their outcome data were comparable at term age, the data from these two groups were combined for analysis in this study. Morbidity data consisted of length of hospital stay, duration of respiratory support (i.e., ventilation, continuous positive airway pressure [CPAP] and oxygen use), prevalence of neonatal diseases including patent ductus arteriosus (PDA) requiring medication or surgery, BPD (oxygen requirement for ≥ 28 days plus treatment with $<30\%$ oxygen