



## A randomized controlled trial of clinic-based and home-based interventions in comparison with usual care for preterm infants: Effects and mediators



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### ABSTRACT

This study examined the effects and mediators of a clinic-based intervention program (CBIP) and a home-based intervention program (HBIP) compared with usual care in very-low-birth-weight (VLBW) preterm infants on developmental and behavioral outcomes at 24 months of age (corrected for prematurity). In this randomized controlled trial, VLBW preterm infants received either CBIP ( $n = 57$ ), HBIP ( $n = 63$ ), or usual care ( $n = 58$ ) from hospitalization to 12 months. At 12 months, infant emotional regulation was assessed using the toy-behind-barrier procedure and dyadic interaction was observed during free play. At 24 months, infant developmental and behavioral outcomes were assessed using the Bayley Scales of Infant and Toddler Development- 3rd edition and the Child Behavior Checklist for Ages 1.5–5, respectively. Compared with infants under usual care, the CBIP-group infants showed higher cognitive composite scores (difference, 95% confidence interval (CI) = 4.4, 0.8–7.9) and a lower rate of motor delay (odds ratio (OR), 95% CI = 0.29, 0.08–0.99); the HBIP-group infants had lower sleep problem scores (difference, 95% CI = -1.4, -2.5 to -0.3) and a lower rate of internalizing problems at 24 months (OR, 95% CI = 0.51, 0.28–0.93) (all  $p < .05$ ). The CBIP's effect on cognitive outcome was attenuated when maternal or dyadic interactive behavior was considered; whereas the HBIP's effect on sleep and internalizing behavior was attenuated when duration of orientation to a toy or object was considered. In conclusions, interventions enhanced the cognitive, motor, and

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behavioral outcomes of VLBW preterm infants. The effects on cognitive and behavioral outcomes might be mediated by early-improved mother–infant interaction and infant emotional regulation, respectively.

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## 1. Introduction

Preterm births with very-low-birth-weight (VLBW; birth weight < 1500 g) exert unfavorable effects on not only maternal psychological wellness (Saigal & Doyle, 2008) and mother–infant interaction (Bozzette, 2007) but also child developmental outcomes (Aarnoudse-Moens, Weisglas-Kuperus, van Goudoever, & Oosterlaan, 2009; Saigal & Doyle, 2008). In Western countries, various interventions have been developed for preterm infants that yielded small motor benefits in early infancy and moderate cognitive benefits from infancy to preschool age (Orton, Spittle, Doyle, Anderson, & Boyd, 2009; Spittle, Orton, Anderson, Boyd, & Doyle, 2012; Vanderveen, Bassler, Robertson, & Kirpalani, 2009), but inconclusive effects on behavioral outcome (Blair, 2002; Brooks-Gunn, Klebanov, Liaw, & Spiker, 1993; Kaarensen et al., 2008; Kleberg, Westrup, & Stjernqvist, 2000; Koldewijn et al., 2010, 2005, 2009; Nordhov, Ronning, Ulvund, Dahl, & Kaarensen, 2012; Spencer-Smith et al., 2012; Spittle et al., 2010; Westrup, Bohm, Lagercrantz, & Stjernqvist, 2004). The investigation in Eastern societies has been limited to only one study in China, which showed cognitive benefits (Bao, Sun, Wei, & Co, 1999). Given substantial variations in health care systems and family structures among societies, the effect of intervention programs needs to be investigated in relevant cultural contexts.

Despite documented effectiveness, the social and developmental pathways underlying the interventions remain unclear. Behavioral interchanges between an infant and his/her caregiver have been proposed as a vehicle for the development of cognitive, language, psychomotor, and socio-emotional functions (Browne, 2003; Dunn, Reilly, Johnston, Hoopes, & Abraham, 2006; Geva & Feldman, 2008; Ramey, Bryant, Sparling, & Wasik, 1984). Early responsive parenting and focused infant attention during dyadic interaction have been found to predict later favorable cognitive, language, and behavioral outcomes in both term and preterm infants (Forcada-Guex, Pierrehumbert, Borghini, Moessinger, & Muller-Nix, 2006; Lawson & Ruff, 2004; Schmidt & Lawson, 2002; Smith, Landry, & Swank, 2006). One study of preterm infants reported that improvement in maternal responsiveness at 30 months of age mediated an intervention's effect on cognitive outcomes at 36 months of age (Mahoney, Boyce, Fewell, Spiker, & Wheeden, 1998). In addition, emotional regulation has been proposed as the antecedent variable of behavioral outcomes (Geva & Feldman, 2008; Mahoney et al., 1998). Inadequate stress regulatory behavior in the first year of life was found to predict behavioral problems at 5 years of age in preterm infants (Feldman, 2009). Partnership with a parent and advanced attention control for emotional regulation, which form the foundation of subsequent development (Carpenter, Nagell, & Tomasello, 1998; Lowe, Erickson, & MacLean, 2010) and behavior (Bell & Deater-Deckard, 2007; Calkins & Fox, 2002), are developed in infants at 12 months of age. This time period therefore provides a critical window to investigate the social and developmental pathways underlying effective interventions.

Early intervention for preterm infants in Taiwan has been limited to in-hospital developmental care at certain medical centers. To replicate the benefits of home visits from Western experiences (Brooks-Gunn et al., 1993; Koldewijn et al., 2010; Newnham, Milgrom, & Skouteris, 2009) and to adapt intervention programs to the high accessibility of clinic visits for after-discharge services in Taiwan, we developed a clinic-based intervention program (CBIP) and a home-based intervention program (HBIP) for VLBW preterm infants in Taiwan from hospitalization until 12 months of age (corrected for prematurity) (Chen et al., 2013). The CBIP and HBIP contained similar child-, parent- and dyad-focused services and the interventions after discharge were respectively delivered at clinic and at home. Compared with the usual care program (UCP), these programs significantly reduced the incidence of retinopathy and feeding desaturation, and enhanced weight gain in the neonatal period (Chen et al., 2013).

This study therefore extended our research to examine the long-term effectiveness of the CBIP and HBIP in comparison with UCP on VLBW preterm infants' developmental and behavioral outcomes at 24 months of age. Additionally, this study investigated whether mother–infant interaction and infant emotional regulation at 12 months mediated the interventions' effects on subsequent developmental and behavioral outcomes for the infants. We expected that the CBIP and HBIP would enhance infants' developmental and behavioral performance at 24 months of age through better mother–infant interaction and infant emotional regulation at 12 months of age.

## 2. Methods

### 2.1. Participants

This randomized controlled trial (RCT) enrolled VLBW preterm infants from three hospitals in northern Taiwan from 2006 to 2008 (Chen et al., 2013). The inclusion criteria were birth weight < 1500 g, gestational age < 37 weeks, admission to the study hospital within 7 days of birth, singleton birth or the first child of twins or multiples (equal contribution from each family to the data), and an absence of congenital anomalies or severe neonatal diseases (seizure, hydrocephalus, ventriculoperitoneal shunt, grade III-IV intraventricular hemorrhage, and necrotizing enterocolitis). Infants exhibiting persistently unstable physiological conditions at a post-menstrual age (PMA) of 36 weeks, discharged from the hospital at a PMA of 44 weeks or older, or having a late-developed severe neonatal disease such as periventricular leukomalacia and stage

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