



A randomized controlled trial of routines-based early intervention for children with or at risk for developmental delay



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ABSTRACT

Routines-based early intervention (RBEI) for children with or at risk for developmental delay encourages collaboration between professionals and families to enhance children's participation in family routines with family-selected goals. We conducted the first single-blinded randomized control trial to examine the effectiveness of a 6-month RBEI vs. traditional home visiting (THV), which uses a curriculum focused on children's developmental domains. Thirty-one families with children aged 5–30 months (mean age 17.4 months) with or at risk for developmental delay were randomly assigned to an RBEI group ($n = 15$) or a THV group ($n = 16$). The enrolled children were evaluated using the Chinese version of Pediatric Evaluation of Disability Inventory (PEDI-C) and the Comprehensive Development Inventory for Infants and Toddlers (CDIIT) at 5 time points. Two-way mixed analysis of variance (ANOVA) was used to examine the group by stage interactions. Goal Attainment Scaling (GAS) and the Canadian Occupational Performance Measure (COPM) were applied to explore between-group differences on individualized goal achievement. PEDI-C showed that the RBEI group had a faster progress rate in self-care functions and independence in social functions in the first 3 months of intervention and at the 6-month follow-up. The RBEI group also scored higher on the GAS in the first 3 months of intervention. However, between-group differences in changes in the developmental domains on the CDIIT were not significant. Thus, RBEI was more effective than THV in promoting functional outcomes and reaching family-selected goals, while both interventions allowed equal improvement in developmental domains.

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1. Introduction

Early Intervention (EI) programs with randomized controlled trials (RCTs) that begin in the first three years of life have been effective for children who are socially or biologically at risk for developmental delay, especially in traditional measures of development, such as cognitive, motor, and social-emotional skills (Barnett, 2011; Spittle, Orton, Doyle, & Boyd, 2007). Recent advances in EI programs, however, advocate functional outcomes (Maxwell & Granlund, 2011; Palisano et al., 2012),

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which are relevant to children's daily routines and related to participation in daily living. To maximize functional outcomes, the content of EI has changed from the provision of child-focused to family-focused services, proactively supporting families in providing their children experiences and opportunities for actively learning through daily routines and with the functional goal of promoting children's participation in daily routines and appropriate interaction with people and the environment (Dunst, Bruder, Trivette, Raab, & McLean, 2001; Dunst, 2009; Guralnick, 2008). The basis for this changing model is drawn from theories on ecological systems (Bronfenbrenner, 1979), empowerment (Rappaport, 1981), social support (Gottlieb, 1981), help-giving (Brickman et al., 1982), and family strength (Stinnett & DeFrain, 1985), which provide a family-focused intervention.

Recently developed EI programs focus primarily on these functional outcomes and support the evolution of the roles of interventionists and families. The family's role in EI is to broaden the children's opportunities for active exploration and learning in daily living activities (Dirks & Hadders-Algra, 2011; Hadders-Algra, 2011; McWilliam, 2010; Melnyk et al., 2004). In contrast to the role of "Parent as Teachers" (Olds, Sadler, & Kitzman, 2007) or as co-teacher/co-therapists (Dirks & Hadders-Algra, 2011) in traditional EI programs, the family in the newly developed EI programs have the autonomy to identify children's problems according to their own child-rearing perspectives and make decisions about intervention strategies (Dirks & Hadders-Algra, 2011). The role of the interventionist has also changed from being an instructor or a teacher to being a collaborator working with the family (Dirks & Hadders-Algra, 2011; Hadders-Algra, 2011). Under the context of equal partnership with the family, interventionists now use coaching techniques to empower the family rather than direct instruction to educate them (Dirks & Hadders-Algra, 2011; Hadders-Algra, 2011; Peterson, Luze, Eshbaugh, Jeon, & Kantz, 2007).

The routines-based early intervention (RBEI) program is one of these recently developed approaches that focuses on achieving functional outcomes, namely child's independence, social relationships with others, and parents' satisfaction with routines, by providing the children with learning opportunities in naturally occurring contexts (i.e., daily routines) and systematically uses collaboration and coaching to set functional goals and implement service plans with the family (McWilliam, 2010). Routines are defined as activities with temporal regularity (Sytsma, Kelley, & Wymer, 2001), such as those that predictably occur in the same order about the same time each day. These routines reflect the common goals of the family, for example, preparing meals or getting the children ready for bed, and provide a natural learning context. RBEI begins with a Routines-based interview (RBI) with families and usually incorporates home visits (McWilliam, Casey, & Sims, 2009; McWilliam, 2010). RBI is an informal semi-structured method of gathering information about a child and the family's daily routine, which guides the parents or caregivers to report the tasks and the manner in which the children accomplish these tasks in the routine; it allows the interventionists to guide parents to determine and prioritize outcomes (McWilliam, 2010). The RBEI emphasizes children's success in performing routines in the current environment as functional outcomes, which can be identified during RBI. In comparison to traditional domains that early interventions used as primary outcomes, such as fine motor, gross motor, communication, cognition, and behavior (Blauw-Hospers & Hadders-Algra, 2005; Brooks-Gunn et al., 1994; Peacock, Konrad, Watson, Nickel, & Muhajarine, 2013), the functional domains were found to be more meaningful for families and children. Nevertheless, the traditional domains are not completely eliminated in RBEI, but incorporated within the functional domains. The RBEI process interventions include the current trends of family-centered practice and parental empowerment by incorporating intervention into children's or families' daily routine as per schedules in the natural home setting. This approach provides the child opportunities to acquire survival skills repeatedly over time in the natural home environment. The learned skills are thus expected to sustain in real life for a longer time. Consequently, functional and developmental outcomes are considered to be the primary and secondary outcomes in RBEI, respectively.

Most of the traditional EI programs also incorporate home visits, in which the professionals or paraprofessionals give instructions to the family or introduce a well-designed curriculum for children in the home setting so that the family may increase their sense of control or comfort (Peacock et al., 2013). Traditional home visiting (THV) has also demonstrated promising effects through RCTs in socially (Peacock et al., 2013) or biologically at risk children (Brooks-Gunn et al., 1994), particularly in the cognitive domain.

A high-quality study design (i.e., RCTs) with longitudinal follow-up provides the best evidence for the immediate and lasting effects of EI programs (Barnett, 2011; Olds et al., 2007). RCTs have been used to examine the effectiveness of emerging EI programs compared with traditional services (Blauw-Hospers, de Graaf-Petersa, Dirks, Bos & Hadders-Algra, 2007; Hielkema et al., 2011). The results show similar improvements in functional outcomes for the new programs and the traditional services in preschoolers (Law et al., 2011), and better cognitive and functional mobility outcomes in infants, with sustained effects observed at follow-up assessments (Blauw-Hospersa et al., 2007; Hielkema et al., 2011). However, these RCTs were limited to neurologically at risk children and used the intervention strategy of changing the task and environment to facilitate self-produced motor activities (Blauw-Hospersa et al., 2007; Hielkema et al., 2011; Law et al., 2011).

In order to bring RBEI programs into evidenced-based practice or policy, RCTs should be replicated in light of essential elements and target populations (Olds et al., 2007). Furthermore, the dose-response relationship of the intervention intensity or duration should be investigated with regard to cost and effectiveness in the practice of EI (Barnett, 2011; Law et al., 2011; Peacock et al., 2013). Some studies exploring the effect of treatment dosage on cerebral palsy indicate that strong doses or long treatment durations do not necessarily guarantee more benefits. DeLuca, Case-Smith, Stevenson, and Ramey (2012) reported equally positive effects of constraint-induced movement therapy across multiple outcomes for interventions lasting 6 h/day and 3 h/day. Novak, Cusick, and Lannin (2009) reported that the effect of home programs for children with cerebral palsy was larger in a 4-week treatment than in the 8-week treatment group. However, the

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