Research in Developmental Disabilities 34 (2013) 3112–3123

Contents lists available at SciVerse ScienceDirect

Research in Developmental Disabilities

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

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ARTICLE INFO

Article history:
Received 30 April 2013
Received in revised form 25 June 2013
Accepted 25 June 2013
Available online

Keywords:
Early intervention
Routines-based early intervention
Developmental delays
Home visiting

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.

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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http://dx.doi.org/10.1016/j.ridd.2013.06.037

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

minimum threshold for efficacy in terms of the duration of RBEI programs is unknown. Despite the existing evidence about neurologically at risk children, there is no evidence demonstrating the effectiveness of RBEI among a broader range of socially and biologically at risk children. Furthermore, it is still unclear whether an RBEI program offers more benefits than THV or if the modifiers of the dose-relationship are similar. To fill this gap, the present study explored the effectiveness of RB compared with THV programs in children with or at risk for developmental delay and less than 3 years old, using an RCT. We hypothesized that the group receiving RBEI would have better functional outcomes, as opposed to the traditional domain outcomes, compared with group receiving THV.

2. Materials and methods

2.1. Participants

Forty-five families of children with or at risk for developmental delay were referred from 1 medical center, 3 hospitals, 2 institutes, and 2 agencies of the government social welfare system in Taiwan. The study was approved by institutional human ethics review committee of Chang Gung Memorial Hospital. Children had to be less than 36 months of age and the recipient of a *Z*-score on the screening test of the Comprehensive Developmental Inventory for Infants and Toddlers (CDIIT) (Wang et al., 1998) of less than −1 for at least 1 domain. The children were allowed to attend any regular intervention services during this study. Children who received aggressive treatment, such as Botox injections, were excluded, as were children with a progressive disease, such as muscular dystrophy, which was expected to cause a decrease in physical condition over time. Five children were not enrolled because the parents declined participation and 2 were excluded due to age. Thirty-eight of the children of the referred families met the selection criteria and their parents agreed to participate in this study.

2.2. Design and procedures

This study was a single-blinded RCT with a three-month baseline, a 6-month intervention, and a 6-month follow-up period. Table 1 lists the program characteristics, the role of the family and interventionist, and the procedures of the RBEI and THV groups. The 38 children were randomly assigned to the RBEI and THV groups. For both groups, the children's outcomes were measured with 2 norm-referenced tests and 2 individualized goal achievement measures (described in Section 2.3). The children were assessed with the norm-referenced measures at five time points by an assessor who was blind to group assignment and intervention procedures. The 5 time points were baseline (Time 1), pre-intervention (Time 2), mid-term intervention (Time 3), post-intervention (Time 4), and follow-up (Time 5) (Fig. 1). Four stages were defined: Stage I was the three-month baseline period (Time 1 to Time 2) and Stages II (Time 2 to Time 3) and III (Time 3 to Time 4) covered the 6-month intervention period, which was divided into 2 stages by a mid-term assessment (Time 3) to investigate the dosage-relationship for intervention. Stage IV (Time 4 to Time 5) was designed as a 6-month follow-up period after intervention to

Table 1
Comparison of the features and procedures of the routines-based early intervention (RBEI) and traditional home visiting (THV).

	RBEI	THV
Program characteristics	Family-focused	Child-focused
Role of family	Autonomy to identify child's problems with family routines, select functional goal, and design strategies	A co-interventionist to follow the interventionist
Role of interventionists	Coach all family members	Teach or instruct parents
Outcome assessment and measures	PEDI-C and CDIIT by a blind assessor at 5 time points	
	Routines-based interview by the trained interventionist	Curriculum-based developmental evaluation by the trained interventionist
Goal setting and goal achievement measures	Family was supported by the interventionist to identify functional goals	Parents were instructed by the interventionist to identify developmental goals
	Measured by GAS and COPM at 2 intervention stages (Stage II and III)	
	Interventionist collaborated with family to design intervention strategies	Interventionist selected intervention strategies from the curriculum guide
Intervention	Strategies were embedded in family routines and procedures were written for families to follow	Corresponding strategies were listed for parents
	Bi-weekly home visits during 6 months of intervention	
	A diary containing a list of specific strategies with corresponding goals was provided to the family for recording the implementation of selected strategies	

Note: Shaded areas represent common characteristics of the 2 intervention groups.

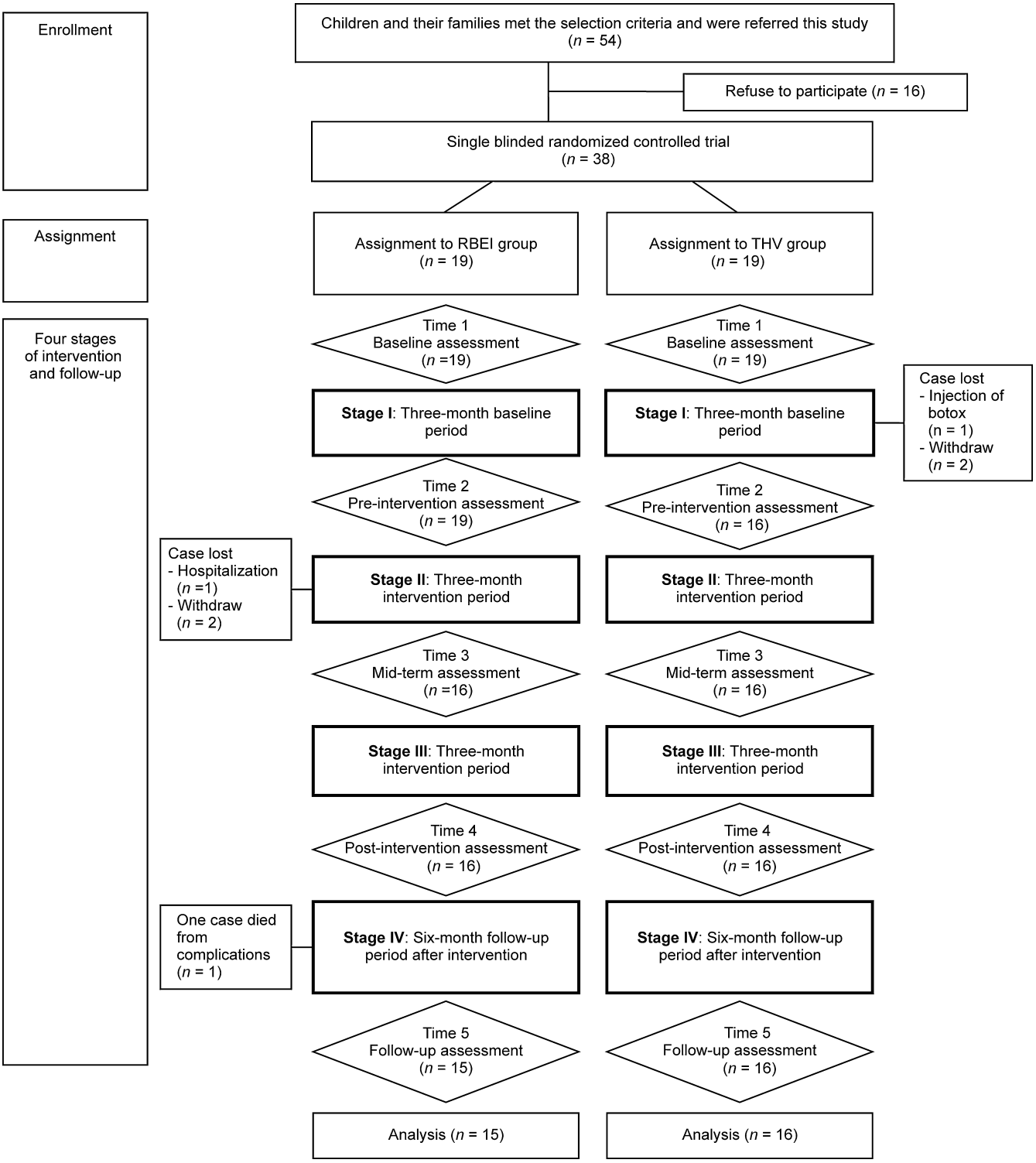

Fig. 1. Flow diagram of the randomization procedure in this study. RBEI: routines-based early intervention and THV: traditional home visiting.

explore the sustained effects of intervention. However, the time periods varied due to uncontrolled conditions, such as child illness and parent schedules. Two trained home visitors were responsible for the RBEI and THV groups, respectively. The home visitors conducted initial interviews with families immediately following the Time 2 assessment, helped the families set goals at Time 2 and Time 3, measured goal achievements at Time 3 and Time 4, and implemented bi-weekly home visits during the 6-month intervention period. The initial interviews contained an RBI for the RBEI group and a curriculum-based developmental evaluation for the THV group. Some children were lost to follow up at the final assessment for the reasons described in Fig. 1.

Table 2
Demographic characteristics of children and their families at Time 1.

Variables	RBEI group ($n = 15$)	THV group ($n = 16$)	p value
Chronological age (months) (mean ± SD)	16.8 ± 6.8	17.9 ± 5.5	0.632[a]
Corrected age (months) (mean ± SD)	16.1 ± 7.1	16.8 ± 6.2	0.753[a]
Gender (n) (boys/girls)	10/5	10/6	0.553[b]
Gestational age (weeks) (mean ± SD)	34.9 ± 3.9	34.8 ± 5.2	0.945[a]
Birth weight (g) (mean ± SD)	2154.7 ± 853.4	2219.8 ± 969.1	0.847[a]
Diagnosis (n)			
Developmental delay without a defined etiology	5	3	0.607[b]
Down syndrome	1	0	
Cerebral palsy	0	1	
Hydrocephalus	1	0	
Preterm	7	7	
Congenital heart disease	0	1	
Chromosome abnormally	0	1	
Others[c]	1	3	
Outcomes measures at assignment			
PEDI functional skill			
Self-care	18.47 ± 12.24	14.1 ± 9.57	0.275[a]
Mobility	31.26 ± 24.49	29.23 ± 19	0.797[a]
Social function	23.24 ± 12.10	19.78 ± 9.57	0.383[a]
PEDI caregiver assistance			
Self-care	10.55 ± 18.34	4.65 ± 11.44	0.288[a]
Mobility	21.24 ± 21.64	19.89 ± 22.04	0.865[a]
Social function	7.01 ± 13.36	3.98 ± 7.46	0.437[a]
CDIIT			
Cognition DQs	53.7 ± 33.51	63.7 ± 21.88	0.330[a]
Language DQs	74.47 ± 17.78	63.81 ± 18.01	0.108[a]
Gross motor DQs	60.59 ± 31.98	47.7 ± 37.13	0.310[a]
Fine motor DQs	67.39 ± 21.67	61.7 ± 28.29	0.537[a]
CDIIT-whole DQs	59.84 ± 19.92	51.2 ± 23.81	0.283[a]
Social Economic Status (n) (I/II/III/IV/V)	0/4/6/1/4	1/8/4/1/2	0.498[b]

Notes: RBEI: routines-based early intervention; THV: traditional home visiting; PEDI-C: Pediatric Evaluation of Disability Inventory-Chinese Version. CDIIT: Comprehensive Developmental Inventory for Infants and Toddlers, DQ: developmental quotients, and SS: scale scores.
[a] Independent t-test.
[b] Chi-square test.
[c] Others include glutaric aciduria type I, William's syndrome, Edwards syndrome, and arthrogryposis multiplex congenita.

Table 2 lists the basic information obtained at the beginning of this study for the families and children that completed the final assessment. The outcome measures included (1) the primary or functional outcomes, including child's independence, the child's social relationships, and the parent's satisfaction with the child's progress and (2) secondary or traditional outcomes (the children's development in the domains of cognitive, language, gross motor, and fine motor skills). A power analysis was conducted with an a priori alpha of 0.05, power of 0.80, and a small effect size of 0.30 showed that a sample size of 24 was needed to conduct a mixed-model analysis with four repeated measures and 2 groups (GPower, 3.1.3, Franz Faul Universität, Kiel, Germany, 2010).

2.3. Assessment

2.3.1. Demographic characteristics for children and their families

The demographic characteristics of children and families were collected at the time of recruitment (Table 2). The child's birthday and gestational age were used to calculate the chronological age and corrected age, respectively. Gestational age and diagnosis were obtained from medical records. Families' socioeconomic status (SES) was classified according to predefined levels ranging from I to V, with I indicating the highest level of SES (Hollingshead, 1975; Rin, Schooler, & Caudill, 1973).

2.3.2. Primary outcomes

The primary outcomes were defined as the outcomes related to meaningful daily functions, which reflected children's capability and performance in the current environment, the family's perceptions about and satisfaction with the children's changing abilities (described in 2.3.2.1–2.3.2.3).

2.3.2.1. Pediatric Evaluation of Disability Inventory-Chinese version (PEDI-C). The Pediatric Evaluation of Disability Inventory (PEDI) is a widely used outcome measure for children with developmental disabilities. It is usually used in an interview with the primary caregivers (Haley, Coster, Ludlow, Haltiwanger, & Andrellos, 1992). The Chinese version in Mandarin, the PEDI-C,

has been cross-culturally adapted (Chen, Hsieh, Sheu, Hu, & Tseng, 2009), and the Taiwanese form has been psychometrically validated (Chen et al., 2009; Chen, Tseng, Hu, & Koh, 2010). The PEDI-C contains three domains: (1) Self-care, (2) Mobility, and (3) Social function. We measured children's capability and performance in these three domains with the scale scores of the Functional Skills Scales (FSS) and the Caregiver Assistance Scales (CAS) in the PEDI-C. The FSS are designed to identify the child's capability to participate in daily functions. The CAS measures the performance of children with respect to the amount of assistance they need to carry out functional activities. Higher scores on the FSS and CAS reflect superior capability and performance (or independence) (Tseng & Chen, 2012).

2.3.2.2. Goal Attainment Scaling (GAS). Goal Attainment Scaling (GAS) has been developed to scientifically measure individual progress on tailor-made goals (Kiresuk & Sherman, 1968). GAS was useful in this study because the home visitors collaborated with the families to establish individualized goals for each child. The five levels of outcome for each goal—expected (0), somewhat more than expected (+1), much more than expected (+2), somewhat less than expected (−1), much less than expected (−2)—are accompanied by behavior descriptions and a rating of corresponding importance (weighting) at the beginning (Times 2 and 3) of each intervention stage (Stages II and III). Each goal for the intervention was rated at the end of the corresponding stage (Time 3 for Stage II and Time 4 for Stage III). The five levels of scale values and weighting obtained for all of the goals can be transformed into an overall goal attainment standardized *T*-score (Kiresuk & Sherman, 1968; Steenbeek, Ketelaar, Galama, & Gorter, 2007; Turner-Stokes, 2011).

2.3.2.3. Canadian Occupational Performance Measure (COPM). The COPM was used to interview the parents about the child's functional challenges to arrive at a parental rating of the child's performance, and to measure parental satisfaction with the child's performance, on a 10-point scale at the beginning and end of the intervention (Law, Baptiste, Polatajko, & Pollock, 2005). The sum of the change in the parent's performance and satisfaction ratings were averaged by the number of problem areas in which the parent perceived positive changes in the child's performance and indicated satisfaction with these changes (Law et al., 2005). Aligned with GAS, the specified goals for Stages II and III were rated on 10-point scales at the beginning (Times 2 and 3) and the end (Times 3 and 4) of the intervention.

2.3.2.4. Routines-based interview (RBI). A routines-based interview (RBI) is method of systematically gathering information from families and planning intervention strategies in a semi-structured interview (McWilliam et al., 2009). It has 6 well-articulated steps (beginning statements, routines as the agenda, information from routines, satisfaction with routines, concerns and priorities, outcome writing) for completing the assessment (for details, please see McWilliam et al., 2009). The home visitor in the RBEI group coached the families in identifying problems, setting goals, and selecting strategies, and acted as an equal partner in conversations and discussions. The goals were listed with the consent of the parents and were measured with GAS and the COPM described in Sections 2.3.2.2 and 2.3.2.3.

2.3.3. Secondary outcomes

The secondary outcomes were the traditional domains of measurement of child development in cognitive, language, gross motor, and fine motor skills. Most of these functions reflect the expected achievements by age, performed in a standardized test environment, and using standardized tools.

2.3.3.1. Comprehensive Development Inventory for Infants and Toddlers (CDIIT). As a secondary measure, this study used the cognition, language, gross and fine motor subtest of the CDIIT (Wang, 2003), which is a well-designed developmental test, previously standardized in a sample of 3703 children in Taiwan, that covers five developmental areas: cognition, language, motor, social, and self-help skills (Wang et al., 1998). The CDIIT has sound concurrent validity (Liao, Wang, Yao, & Lee, 2005; Liao, Yao, & Wang, 2008), construct validity (Hwang, Weng, & Liao, 2010), and diagnostic validity and reliability (Wang et al., 1998; Wu et al., 2005). All the items were tested with the standardized test materials and procedures except a portion of the language items, which required the parents' report of skills observed outside the time of the test. The developmental quotients and developmental ages are derived according to the manual created by Wang et al. (1998).

2.3.3.2. The Carolina Curriculum for Infants and Toddlers with Special Needs-Chinese version (CCITSN-C). The Carolina Curriculum for Infants and Toddlers with Special Needs (CCITSN) is designed to provide curricular intervention strategies for children with impairments from birth up to 36 months (Johnson-Martin, Attermeier, & Hacker, 2004). This study selected the assessment in CCITSN for the THV group partly because it has been translated into Chinese (CCITSN-C) (Chang & Huang, 2008). The CCITSN/CCITSN-C uses a comprehensive progress chart of the child's developmental problems in the traditional developmental domains, such as cognition, gross and fine motor, and communication skills (Chang & Huang, 2008; Johnson-Martin et al., 2004). The goals of the intervention are set at the skill level immediately above the child's current ability. For example, the child was assessed by CCITSN-C using the progress chart, and the first items in the sequence of cognitive and communication domain that the child had not passed were "point to five body parts on request" and "match objects to their sounds" respectively. These two items were the developmental skills just above the child's current ability, and were potentials goals for intervention. The corresponding activities for each developmental skill and material needed for implementing the intervention are also available in CCITSN-C.

2.4. Intervention

Both the RBEI and THV groups received bi-weekly home visits by the 2 trained home visitors for 6 months (Stages II and III). The home visitors were supervised for the 6 months of home visits and supported by a team of professionals including special education teachers, physical therapists, occupational therapists, doctors, and nurses. Additionally, the home visitor for RBEI group received training on the RBI (McWilliam et al., 2009) and techniques for coaching families (Dirks, Blauw-Hospers, Hulshof, & Hadders-Algra, 2011; Rush & Sheldon, 2011), and the home visitor for THV group was trained on the CCITSN-C (Johnson-Martin et al., 2004). Table 1 lists the different elements in RBEI and THV. The home visitor of the RB group conducted the RBI assessments (McWilliam et al., 2009) and used coaching techniques to collaborate with families on goal-setting and intervention strategies at the beginning of Stages II and III, followed by the bi-weekly home visits focused on guiding and checking the implementation of these intervention strategies in home. Coaching is guidance that focuses on the empowerment of families and facilitates their participation in the decision-making and planning of the intervention activities for their child (Rush & Sheldon, 2011). For example, the interventionists guide the family to discuss the child's or family's routines from the beginning of a day following the suggested guidelines (McWilliam et al., 2009), and the family is encouraged to identify certain difficulties with smooth performance of specific routines, such as children's feeding problems or difficulty getting to sleep. Further, the interventionists encouraged the families to describe the context (with whom and where) of experiencing the difficulties and then supported the families to select several main difficulties and prioritize the goals directed by those difficulties that needed to be resolved. For the THV group, the assessment interview focused on assessing the child's abilities with the curriculum program guide of the CCITSN-C was followed by bi-weekly home visits focused on giving instructions to caregivers and checking the implementation of intervention strategies in the home. The interventionists helped the parents to choose several developmental skills that were more advanced compared to the child's current level in each domain of CCITSN-C as the goals. Each assessment interview lasted 1.5–2 h. For the RBEI group, the home visitor discussed intervention strategies and how they could be embedded in the child's daily routine with the parents. The home visitor listed sequentially the processes of the routine, modified with some intervention strategies, to help the parents learn. For the THV group, the home visitor provided and listed strategies for caregivers without a specific focus on the normal routine. Both the RBEI and THV groups were required to complete a daily log about the implementation of the intervention strategies.

2.5. Statistical analyses

Analyses were conducted using Statistical Package for the Social Sciences (SPSS) version 17.0 (SPSS, Inc., Chicago, IL, USA). To examine the demographic characteristics of children and their families in both groups at Time 1, we conducted independent *t*-tests and chi-square tests for continuous and categorical data, respectively. For the CDIIT and PEDI-C, the Proportional Change Index (PCI), a valid method to examine EI program effects (Hauser-Cram & Krauss, 1991; Wolery, 1983), and the ratio of developmental gains divided by the exact duration of the stage (calculated in months) were derived for Stages I–IV (Fig. 1). Thus, the PCI represents the speed of progress over time for each stage and can minimize the influence of minor variations in the duration of each stage.

A two-way mixed analysis of variance (ANOVA) with repeated measures (stage) was conducted to examine the main effects of group (RBEI vs. THV), stages (I–IV), and the group × stage interactions with corresponding effect sizes (Cohen's f^2) (Cohen, 1988). For Cohen's f^2, effect sizes of 0.02, 0.15, and 0.35 are considered small, medium, and large, respectively (Cohen, 1988). When the group × stage interactions were significant, repeated measures ANOVAs were run for each group with Tukey's post hoc analysis.

To investigate the dose-relationship effects of the intervention, independent *t*-tests were used to examine the between-group differences for stage II (the first 3 months of the intervention) and stage III (the latter 3 months of the intervention) for all the outcome measures, including the rates of progress in CDIIT and PEDI-C, the GAS scores, and the COPM mean change scores. Effect sizes were calculated with Cohen's *d*, where 0.2–0.3 is considered a small effect; 0.5, a medium effect; and ≥0.8, a large effect (Cohen, 1988).

3. Results

3.1. Baseline data

There were no significant differences in the demographic characteristics of children and their families at Time 1 (Table 2).

3.2. Functional outcomes

The rates of progress in functional domains showed different patterns over the four stages across groups on self-care in FSS (Fig. 2) and social functions on the CAS of the PEDI-C (Fig. 3), indicated by significant group × stage interactions (Table 3). For these 2 functional domains, a repeated-measures ANOVA for the RBEI group showed a higher rate of progress in Stages II and IV compared to Stages I and III, but there were no significant differences between stages in the THV group (Table 3). Functional mobility, in both FSS and CAS, showed generally decreasing rates of progress indicated by main effects on stages.

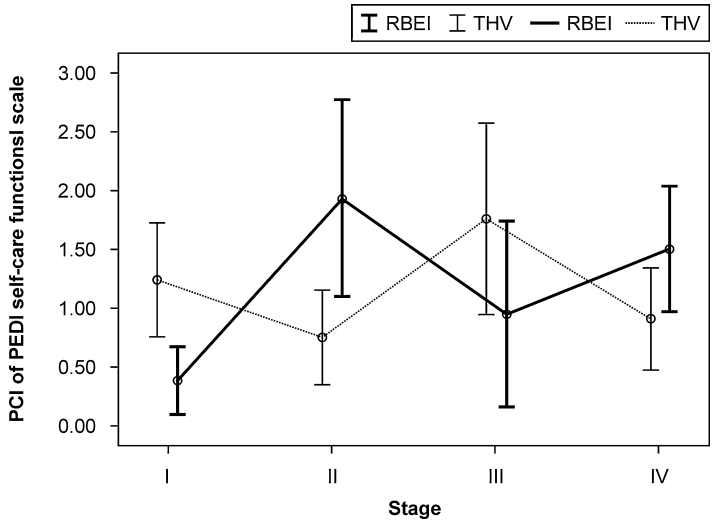

Fig. 2. The proportional change index (PCI) in the four self-care functional skills.

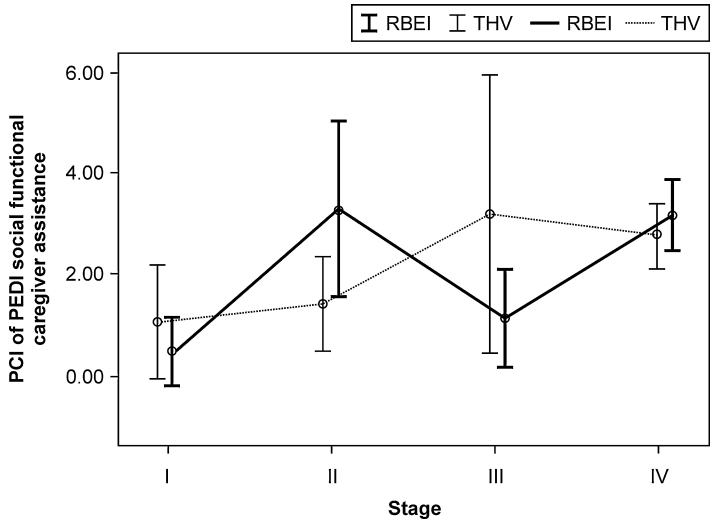

Fig. 3. The proportional change index (PCI) in the four stages for the social function: caregiver assistance.

However, the pattern of the rate of progress over the four stages in the traditional developmental domains was statistically the same in both groups, indicated by the non-significant group × time interactions (Table 3).

Regarding the dose relationship of the intervention, the RBEI group had significantly higher scores on the GAS ($M = 63.5$, $SD = 7.3$) than the THV group ($M = 57.3$, $SD = 7.8$) for Stage II ($p = 0.03$, Cohen's $d = 0.82$), but not for Stage III. Self-care FSS of the PEDI-C ($p = 0.006$, Cohen's $d = 1.07$) and social function CAS of the PEDI-C ($p = 0.027$, Cohen's $d = 0.83$) also indicated a higher rate of progress for the RBEI group in Stage II with large effect sizes. Parental perceived improvement in children's performance and parent satisfaction did not significantly differ between groups in either Stage II or Stage III.

3.3. Outcomes for traditional developmental domains

No significant differences in group by stage interactions for the traditional developmental domains measured by the CDIIT were observed. There were also no significant differences in dose relationship between groups with regard to intervention effects for Stages II or III.

4. Discussion

This was the first RCT to investigate the effects of RBEI for children with or at risk for developmental delay. The findings support the notion that the core element of family coaching and embedding strategies in routines in RBEI are more effective than traditional home visits that focus on providing instructions for child-focused developmental progress regarding functional outcomes. The superior effects of RBEI were shown on specific functional outcomes measured with daily-living

Table 3
The rate of progress in the four intervention stages for routines-based early intervention (RBEI) group and traditional home visit (THV) group.

Outcome measures	RBEI ($n = 15$)				THV ($n = 16$)				Main effects				Interaction effects		
	Baseline period	Intervention period		Follow-up period	Baseline period	Intervention period		Follow-up period	Group		Stage		Group × time		
	Stage I	Stage II	Stage III	Stage IV	Stage I	Stage II	Stage III	Stage IV	$F_{1, 29}$	p value	$F_{3, 29}$	p value	$F_{3, 87}$	p value	ES$_f$[a]
Functional outcomes															
PEDI-C-FSS															
Self-care	0.4 ± 0.5	1.9 ± 1.5 [b,c]	0.8 ± 1.6	1.5 ± 1.1 [b]	1.3 ± 0.9	0.8 ± 0.7	1.7 ± 1.6	0.8 ± 0.9	0.6	0.81	1.1	0.35	5.6	<**0.01**	0.45
Mobility	3.5 ± 3.2	2.3 ± 2.1	1.1 ± 1.2	1.5 ± 1.0	2.3 ± 2.0	2.1 ± 2.0	1.4 ± 1.1	0.9 ± 0.7	0.9	0.36	7.4	<**0.01**	1.2	0.33	0.20
Social function	1.8 ± 1.5	1.8 ± 1.5	1.2 ± 1.1	1.1 ± 0.9	1.7 ± 1.5	1.6 ± 1.0	2.0 ± 1.6	0.7 ± 0.6	0.0	0.85	3.1	**0.03**	1.4	0.25	0.22
PEDI-C-CAS															
Self-care	0.6 ± 2.2	1.4 ± 2.2	1.5 ± 2.1	2.5 ± 1.9	0.5 ± 2.0	2.0 ± 3.6	1.7 ± 8.3	2.2 ± 2.3	0.1	0.82	1.1	0.34	0.1	0.97	0.05
Mobility	3.7 ± 3.8	2.0 ± 3.8	1.3 ± 1.2	1.1 ± 1.7	3.5 ± 3.7	1.1 ± 3.6	1.6 ± 2.1	0.7 ± 1.1	0.4	0.55	5.1	<**0.01**	0.2	0.90	0.08
Social function	0.5 ± 1.2	3.3 ± 3.1 [b,c]	0.8 ± 2.3	3.2 ± 1.3 [b]	1.1 ± 2.1	1.0 ± 2.4	3.2 ± 5.1	2.8 ± 1.2	0.0	0.89	3.4	**0.02**	3.9	**0.01**	0.37
GAS		63.5 ± 7.3[d]	63.9 ±10.1			57.3 ± 7.8	59.7 ± 10.3								
COPM -P		0.4 ± 2.1	1.1 ± 1.7			0.7 ± 2.2	1.0 ± 2.0								
COPM -S		−0.3 ± 1.9	0.0 ± 2.1			0.4 ± 1.9	0.5 ± 1.7								
Developmental outcomes															
CDIIT															
Cognition	0.9 ± 1.0	1.1 ± 1.1	0.7 ± 0.9	0.9 ± 0.6	0.8 ± 0.6	0.8 ± 0.6	0.8 ± 0.7	1.0 ± 0.7	0.1	0.79	0.3	0.85	0.5	0.70	0.13
Language	1.0 ± 0.9	1.5 ± 1.1	0.7 ± 0.6	0.8 ± 0.8	0.8 ± 0.7	0.9 ± 0.7	1.1 ± 0.7	1.0 ± 1.0	0.0	0.94	1.2	0.31	2.4	0.08	0.29
Gross motor	0.6 ± 0.4	1.0 ± 1.1	0.8 ± 1.5	0.6 ± 0.4	0.6 ± 0.6	0.4 ± 0.5	1.0 ± 1. 4	0.7 ± 0.7	0.1	0.77	0.6	0.60	1.1	0.37	0.19
Fine motor	0.6 ± 0.5	0.7 ± 0.6	0.6 ± 0.6	0.8 ± 0.7	0.7 ± 0.5	0.3 ± 0.3	0.9 ± 0.6	0.8 ± 0.6	0.0	0.92	2.2	0.09	2.5	0.06	0.29

Notes: Values are expressed as the change in scale scores divided by time of the PEDI-C and the change in developmental ages divided by time of the CDIIT with mean ± SD.
PEDI-C-FSS: Functional Skills Scores of Pediatric Evaluation of Disability Inventory-Chinese Version; PEDI-C-CAS: Caregiver Assistance Scale of Functional Skills Scores of Pediatric Evaluation of Disability Inventory-Chinese Version; CDIIT: Comprehensive Developmental Inventory for Infants and Toddlers; GA: Goal Attainment Scaling. COPM-P, Performance scores of the Canadian Occupational Performance Measure; COPM-S, Satisfaction scores of Canadian Occupational Performance Measure. The bold values indicate significant p values.

[a] ES$_f$: effect size of interaction effects calculated by Cohen's f^2.

[b] Post hoc of repeated measures ANOVA showed significant improvement compared to Stages I and III ($p < 0.05$).

[c] Independent t-test showed higher rates of progress compare to THV group in stage II ($p < 0.05$).

[d] Independent t-test showed higher scores of progress compare to THV group in stage II ($p < 0.05$).

relevant scales (PEDI-C) and individualized goal achievement scaling (GAS), as opposed to developmental outcomes measured with the traditional domains of child development (CDIIT).

Self-care capability was the only functional skill of the PEDI-C for which RBEI had more beneficial effects than THV. This may be due to the intimate connection between daily routines and self-care for young children, as both cover eating, dressing, bathing, and toilet tasks (Haley et al., 1992). The child's full day may be occupied with these routines and self-care tasks. Embedding the training strategies into the family routines enhances self-care capabilities in a natural context. Among the caregiver assistance domains in the PEDI-C, social function presented a pattern similar to that of the self-care functional skills, reflecting that the parents provided a decreasing amount of assistance during intervention and at follow-up in RE group. The rate of progress in self-care abilities and the decrease in parental assistance in social functions were apparent in the first 3 months of intervention (Stage II). This finding adds to the growing body of research that suggests a "dose–response" relationship of three months may be adequate for optimal progress in these 2 selected functional outcomes. In the latter three months of the intervention (Stage III), progress in these 2 functional areas slowed, but then sped up again in the 6-month follow-up period (Stage IV). The GAS indicated higher achievement in individualized goals in the RBEI than the THV group exclusively during the first three months of the 6-month intervention period. Novak et al. (2009) also found a similar dose effect in conducting home programs for children with cerebral palsy in that the effect sizes of GAS and COPM were larger in the four-week treatment group than in the 8-week treatment group. These functional skills may improve linearly with age, but the rates of change demonstrated a dynamic pattern involving a drop during the latter three months of intervention and a return to higher level in the follow-up period. The mechanism of this change is not clear but it may relate to the temporal nature of a routines-based home visiting program. In the first three months of intervention, the families and the home visitor may collaboratively identify problems with established routines and find appropriate strategies to solve the identified problems. In the latter three months of intervention, some of the easy problems may have been solved, while the more difficult problems may need more time or extensive modification of the routines to continue to see benefits of the intervention strategies. Fortunately, the rate of progress in the follow-up period resulted in sustained effects. Interestingly, this dynamic pattern was not replicated in the THV group.

Our study had common core essential elements for intervention with 2 RCTs using PEDI (Blauw-Hospers, Dirks, Hulshof, Bos & Hadders-Algra, 2011), COPM, and GAS (Novak et al., 2009) as outcomes measures. Compared to the control group, Novak et al. (2009) reported large effect sizes both in COPM (Chen's $d = 1.4$) and GAS (Chen's $d = 17.9$) at 4 week weeks post-intervention among children with cerebral palsy aged 4–12 years. Our findings present a large effect size for GAS (Cohen's $d = 0.82$), self-care FSS of the PEDI-C (Cohen's $d = 1.07$), and social function CAS of the PEDI-C (Cohen's $d = 0.83$) at 3 months post-intervention. However, for infants at high risk for developmental disorder, Blauw-Hospers et al. (2011) found identical improvement measured with PEDI at 3 months post- treatment for either intervention or control groups. Though limited data with similar populations and age levels are currently available to compare the intervention effects, these findings were found to be consistent with previous studies (Sakzewski, Boyd, & Ziviani, 2007; Vos-Vromans, Ketelaar, & Gorter, 2005) suggesting COPM, GAS, and PEDI to be responsive to intervention changes.

In contrast to self-care and social functioning, the rate of progress for mobility function decreased in the functional skills area, accompanied by an increase in the rate of caregiver assistance over the four stages for both groups, although the scale scores gradually improved across the five assessment times ($F = 37.3$, $p < 0.0001$). The equal benefits of the 2 intervention programs in the present study were also reflected by a non-significant group $\times$ time interaction in the functional motor domains. A meta-analysis of the developmental intervention programs for preterm children with no major congenital abnormalities found no effects on motor outcomes in randomized or quasi-randomized trials (Spittle et al., 2007). Other systematic reviews of studies of children in socially high-risk families (Peacock et al., 2013) or children at risk for motor disorder (Blauw-Hospers & Hadders-Algra, 2005) also indicated the controversy and limited effects on motor outcomes measured by traditional development measures. However, the newly developed family-centered program that focuses on coaching families (Dirks et al., 2011) demonstrated an advance in functional mobility compared to traditional therapy for motor development (Blauw-Hospers et al., 2011; Hielkema et al., 2011). However, these studies had a sample consisting of only children at risk for motor disorders. More evidence is needed to determine whether an early intervention program would improve motor functions in young children with or at risk for a broad range of developmental delays.

For the individualized goals, the higher goal achievement indicated by GAS, rather than parental perceived satisfaction and performance indicated by COPM, was found in the RBEI group in the first three months of intervention. The GAS measures goal attainment with objective criteria defined by observable behaviors. However, parent's perception of their child's performance and their satisfaction may depend on more personal expectations for their children. The professional or parental objective assessments and parental subjective rating of child outcomes may not be the same, and the perspective of parents in an RBEI program should be further investigated to understand the mechanism of pattern changes in developmental rates and the discrepancy between objective and subject outcomes.

As researchers have suggested, using high quality-RCTs with longitudinal follow-ups are essential for investigating the effects of specific elements of the EI program (Barnett, 2011; Olds et al., 2007), and this study demonstrated the strengths of RCTs in RBEI. We avoided a potential source of bias by having a test administrator of the CDIIT and the PEDI-C who was blinded to the group assignment and interventions. The design also included a baseline period to compensate for the lack of a non-treatment control group, and the follow-up period was used to assess sustained effects. Regarding the changes in selected outcomes being a true effect of the intervention (Hauser-Cram & Krauss, 1991), we periodically measured the outcomes to explore the effect of change scores in two norm-referenced tests. However, the measurement errors during the

pre- and post-tests are compounded in the change scores rendering the true change scores undetectable in statistical analysis and yielding incorrect results (Hauser-Cram & Krauss, 1991). Researchers have recommended the rate of developmental progress, instead of the change in scores, to avoid this bias (Hauser-Cram & Krauss, 1991; Wolery, 1983). Therefore, we adopted the Proportional Change Index (PCI) (Wolery, 1983) to track growth rates in the development of functional and traditional domains. Thus, the minor intervention duration variations due to scheduling problems were nullified.

The limitations of this study are 2-fold. First, the small sample size and heterogeneity of children with or at risk for developmental delay resulted in large within-group variation. A well-designed RCT would likely reduce this bias. Second, we lacked a non-treatment group, but this was due to important ethical issues related to that the need to provide consistent and continuous treatment for children with or at risk for developmental delay. Further research with more than 1 comparison group would help distinguish the specific benefits of these innovative early intervention approaches.

5. Conclusions

Through an RCT with a follow-up period and proper tracking of the developmental and functional changes, this study demonstrated that routine-based early intervention can have better effects for selected functional outcomes than traditional home visit programs. Furthermore, the effects in functional outcomes were manifest in the first 3 months of intervention and sustained throughout the follow-up period in the RBEI group.

Conflict of interest

There are no conflicts of interest for any author of this manuscript. None of the authors have any financial interest.

Acknowledgments

We thank all the children and parents that participated in the study. This study was funded by the Chang Gung Medical Research Program (No. CMRPD190181) and the National Science Council of Taiwan (No. NSC99-2314-B-182-002). We also thank the research assistants Ni-Pei Tsai and Yu-Hsin Hsieh, and the following participating agencies: An-An Slow Angels' Family Support Association, Department of Physical Medicine and Rehabilitation of En Chu Kong Hospital, Department of Physical Medicine and Rehabilitation of Shin Kong Wu Ho-Su Memorial Hospital, Da Chien Health Medical System, Social Welfare Department of New Taipei City Government, Yilan County Government Social Affairs Department, Taiwan Foundation for the Blind, A-Bao Education Foundation in Taiwan, and Department of Physical Medicine and Rehabilitation of Chang Gung Memorial Hospital.

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