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Original Article

The effect of adding a home program to weekly institutional-based therapy for children with undefined developmental delay: A pilot randomized clinical trial

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Abstract

Background: Early rehabilitation for children with developmental delay without a defined etiology have included home and clinic programs, but no comparisons have been made and efficacy is uncertain. We compared a weekly visit for institutional-based therapy (IT) to IT plus a structured home activity program (HAP).
Methods: Seventy children who were diagnosed with motor or global developmental delay (ages 6-48 months and mean developmental age 12.5 months) without defined etiology were recruited (including 45 males and 23 females). The outcomes included the comprehensive developmental inventory for infants and toddlers test and the pediatric evaluation of disability inventory.
Results: Children who received only IT improved in developmental level by 2.11 months compared with 3.11 months for those who received a combination of IT and HAP ($p = 0.000$). On all domains of the comprehensive developmental inventory for infants and toddlers test, except for self-help, children who participated in HAP showed greater improvements, including in cognition ($p = 0.015$), language ($p = 0.010$), motor ($p = 0.000$), and social ($p = 0.038$) domains. Except on the subdomain of self-care with caregiver assistance, the HAP group showed greater improvement in all the pediatric evaluation of disability inventory subdomains ($p < 0.05$).
Conclusion: Early intervention programs are helpful for these children, and the addition of structured home activity programs may augment the effects on developmental progression.

Keywords: Developmental delay; Etiology; Rehabilitation

1. Introduction

Developmental delays (DD) are common childhood health problems which affect 5−10% of the general pediatric population.[1] DD can be classified as global developmental delay (GDD), mental retardation, developmental language disorder, motor delay (MD), cerebral palsy, autistic spectrum disorder (ASD)/pervasive DD and profound primary sensory impairments.[2] GDD can be defined as DD in two or more domains (gross/fine motor skills, cognition, speech/language, personal/social skills, or activities of daily living).[3] Determining the etiology of DD is a challenging task. Some risk factors for DD have been reported. Tatishvili et al. showed that the most significant single risk factors for abnormal neurodevelopmental outcome were maternal age, chorioamnionitis,

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gestational age <37 weeks, pathological delivery, and a low (<5) Apgar score at 5 minutes after birth.[4] Our previous report showed that poor sucking ability maybe one risk for DD in the future.[5] In GDD and MD, about half of the etiologies could be identified,[6] which include cerebral dysgenesis, hypoxic-ischemic encephalopathy, chromosomal abnormalities, genetic syndromes, neuromuscular disorder, etc.,[7] whereas in ASD and developmental language impairment, only a very low etiologic yield could be defined.[6]

Early intervention (EI) programs are designed to enhance the developmental competence of participants and to prevent or minimize DDs. In the United States, most of EI are home-based services. Collaboration and consultation with the family are the core part of intervention. In Taiwan, however, the most often discussed type of intervention program is rehabilitation, which includes institutional-based programs such as physical therapy, and occupational therapy. This kind of EI program provides intervention service in clinics, and parents/caregivers should bring the children to the institution to receive treatment programs.[8] Most of the studies in the literature are about children with ASD or cerebral palsy.[9,10] Studies on the outcomes of children with GDD or MD are surprisingly few.[11] Early childhood intervention has been shown to have a positive outcome in children with DD.[12,13] However, it is still unclear whether institutional-based services, home-based services or a combination of the two are the most beneficial for children and families.

Recently, pediatric therapists have been using home activity programs (HAPs) more often[14] to treat children with DD because of insurance cutoff and increased case referral.[15] HAPs are specific activities or tasks designed by therapists to help children gain specific goals in the daily livings. In Taiwan, HAPs are usually used as a complementary intervention or as an alternative treatment if caregivers cannot bring children to the institution for regular treatment. Although studies about HAPs alone showed positive effects on developmental outcomes,[14,16] they usually focused on children with cerebral palsy. Most of studies about development delay usually focused on children with specific disorders such as Williams syndrome, ASD or cerebral palsy; little was mentioned about GDD or MD without specific etiology.[16–20]

Clinically, parents usually ask if there is some program exercise which they can do at home. In a study about autism, an extra home-based intervention program was shown to produce significant improvement.[17] Although HAP and institutional-based therapy (IT) have usually been used in combination, there is scant data about the use of both HAP and IT on children presenting with GDD or MD without identified etiologies. The purpose of this study was to clarify the treatment outcome in children diagnosed with GDD or MD without identified etiologies, and to compare the therapeutic results with or without HAP.

2. Methods

2.1. Participants

Children were recruited from the subjects enrolled in the Child Motor Developmental Delay Screening Program of two pediatric rehabilitation centers serving the population of central Taiwan. This study was approved by the Ethics Committee for Human Research of Taichung Veterans General Hospital, Taiwan. The execution duration was from January 2008 to June 2009. After evaluation by a developmental pediatrician based on the guidelines of the American Academy of Neurology,[4] children with suspected development delay were referred to the pediatric rehabilitation department for furthermore intervention. The inclusion criteria were: (1) children living with their parents, (2) children aged between 6 and 48 months, (3) children with a diagnosis of motor developmental delay (MD) or multi-domain developmental delay (GDD) based on the Comprehensive Developmental Inventory for Infants and Toddlers-Diagnostic Test (CDIIT-D). GDD was defined as a significant (two or more standard deviations below the mean or norm) delay in two or more developmental domains. Motor delay was defined as a significant delay in gross and/or fine motor skills with preservation of age-appropriate performance in other developmental domains.[6]

Children who had been diagnosed with cerebral palsy, genetic disorder, congenital deformity, spina bifida or other neuro-musculoskeletal disorders such as muscular dystrophy, mental retardation, developmental language disorder , or pervasive DD were excluded from the study. Children with DD who had participated in a rehabilitation program previously, or parents and children who could not attend the institutional-based program (ITP) one time per week were also excluded. All the subjects were for the first time to be enrolled in EI programs (Fig. 1).

2.2. Randomization

Children who met the inclusion criteria and whose parents signed the informed consent were recruited and randomly assigned to two groups: Group I: institutional-based therapy program (ITP) for 45 minutes each session; Group II: 30 minutes ITP combined with 15 minutes of HAPs. Coin toss was done independently by a rehabilitation nurse to make a randomization table. The sequence of DD children were determined by the date of EI. All children received treatment once a week, and the treatment period lasted for 12 weeks.

2.3. Instruments and evaluation

The demographic characteristics of children and families were collected, including chronological age, gender, risk factors, socioeconomic status and parents' education level. The Comprehensive Developmental Inventory for Infants and Toddlers (CDIIT-D),[21] a norm-referenced measurement and diagnostic tool, was used for developmental assessment. The reliability of this sequence of screening and diagnostic tests has been well established.[22] Standardization is used for the clinical evaluation of children 3–71 months of age. There are five domains in the comprehensive developmental inventory for infants and toddlers test (CDIIT): cognition, language, motor (gross and fine motor), social and self-help. The cognition domain is used to assess the mental capacities,

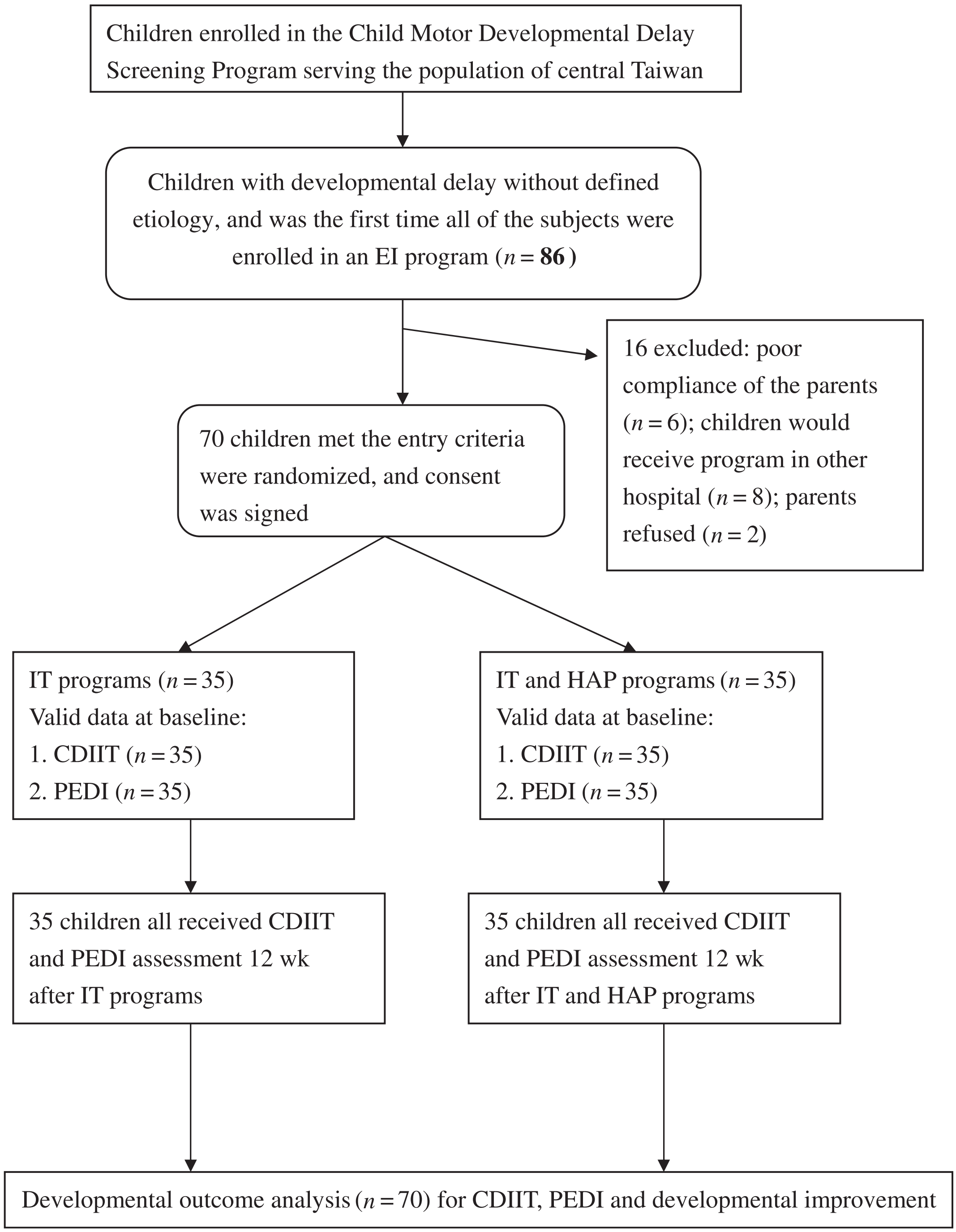

Fig. 1. The consort flow chart of participants in the study. CDIIT = comprehensive developmental inventory for infants and toddlers test; HAP = home activity program; IT = institutional-based therapy; PEDI = pediatric evaluation of disability inventory.

including attention, perception, memory, reasoning, and concepts of color, shape, size and number. The language domain consists of expression and comprehension. The motor domain is divided into gross motor and fine motor. The gross motor subdomain includes gravity compensation, locomotion and body-movement coordination. The fine motor subdomain includes basic hand use and visual-motor coordination. The social domain includes interpersonal communication, affection, personal responsibility and environmental adaptation. The self-help domain assesses the feeding, dressing and hygiene skills.

The Pediatric Evaluation of Disability Inventory (PEDI) is an assessment instrument used for the evaluation of functional skills, caregiver assistance and modifications. In each domain, three subdomains are used for the clinical evaluation of self-care, mobility, and social functions.[23] The PEDI is used for the clinical evaluation of children with disabilities who are 8 months to 6 years of age. In this study, the PEDI scores were obtained by parents' report, and functional skills and caregiver assistance domains were used for the initial and follow-up outcome assessment.

Based on the International Classification of Functioning, Disability and Health,[24,25] activity and participation domains were assessed and home programs were designed by the occupational therapist (first author).[26] Observation about the execution of a task or action of the children and discussions with parents in Group II were held, and goal-directed guidance on how to practice the techniques to achieve specific goals and were instructed in the 15-minute HAP session. For this added 15-minute therapy session, parents received instruction in how to execute HAPs by demonstration by the therapist. Parents/caregiver were asked to do home programs for children every day. The therapists followed up the execution rate once a week.

Execution of the HAP: A Likert 5-point scale was used to assess the execution of HAP in 4 domains: (1) understanding about HAPs, (2) execution frequency, (3) execution intensity, and (4) execution skills (Table 6). Parents were requested to answer questions in these four domains and then score their own answers. Each time, the highest possible score was 20 and the lowest possible score was 4. Parents recorded their answers on the HAP record sheet a total of 5 times (twice a week for 5 times) and the scores were averaged. The average score is shown as the home program execution rate, and it represents the parents' level of compliance.

2.4. Procedures

The children first received assessment by using the CDIIT-D and PEDI for baseline developmental data. Functional therapy, task-specific or activity focused intervention, which are goal or activity-oriented methods to promote better functioning in the context of daily life settings, was used as a major treatment concept in this study.[27–29] Following the International classification of functioning, disability and health model, the activity and participation domains were evaluated by one occupational therapist, who also designed the HAP treatment goals and then discussed them with parents. No more than three therapeutic goals were designated each week, and the parents learned the skills needed to be able to help children at home.

2.5. Statistics

Data were analyzed to determine the association between different treatment programs and developmental outcomes. The chi-square test was used to compare proportions between groups when children were recruited initially. The paired *t* test was used for comparison of pre-test and follow-up test. The Student's *t* test was used for comparing the mean differences of developmental scales between groups. Analysis of covariance (ANCOVA) was used to investigate the interactions between subjects and for control of the pre-test developmental condition. Pearson correlation analysis was used to analyze the association between the HAP execution, CDIIT and PEDI scores. Multivariate linear regression was used to analyze the relations between the pre-intervention score and the improvement. Analyses were performed using the Statistical Package for the Social Sciences [version 13.0; SPSS, Inc., Chicago, IL, USA]. Statistical significance was considered as $p < 0.05$.

3. Results

In total, eighty-six children who met the inclusion criteria were recruited, and 16 children were lost to follow-up. Finally, seventy children (including 45 males and 23 females) were recruited. The mean chronological age of these subjects at initial evaluation was 20.7 months. Participant characteristics including gender difference, family income, parents' education level and children's developmental age are summarized in Table 1. Of the seventy children, forty-five children were boys (64.3%), twenty-two children were diagnosed as having MD, and 48 children were diagnosed as having GDD. The mean chronological age of these subjects at initial evaluation was 20.7 months (standard deviation (SD) = 10.0). The developmental age based on the CDIIT was 12.5 months (SD = 5.9). The average delayed age for these children was 8.2 months. There was no difference in the pre-test PEDI scores of

Table 1
Basic characteristics of the participants

Case numbers	$n = 70$		Group I, $n = 35$		Group II, $n = 35$		*p*
	n	%	*n*	%	*n*	%	
Gender							0.45[a]
Male	45	64.3	21	60.0	24	68.6	
Female	25	35.7	14	40.0	11	31.4	
Developmental diagnosis							0.30[a]
MD	22	31.4	13	37.1	9	25.7	
GDD	48	68.6	22	62.9	26	74.3	
Status of DD							0.81[a]
−2 to−3 SD	35	50	17	48.6	18	51.4	
−3 SD	35	50	18	51.4	17	48.6	
Parents' education level							0.43[a]
<12 yr of education	21	30	9	25.7	12	34.3	
>12 yr of education	49	70	26	74.3	23	65.7	
Family income							0.63[a]
<20,000 USD	36	51.4	19	54.3	17	48.6	
>20,000 USD	34	48.6	16	45.7	18	51.4	
Parents' age							1.00[a]
30 and under	22	31.4%	11	31.4%	11	31.4%	
31 and over	48	68.6%	24	68.6%	24	68.6%	
	Mean	SD	Mean	SD	Mean	SD	*p*
Chronological age	20.7	10.0	21.1	10.2	20.3	10.0	0.34[b]
Developmental age	12.5	5.9	13.0	6.4	12.0	5.4	0.69[b]
Raw scores of functional skills	47.5	34.6	50.9	35.1	44.0	33.6	0.39[b]
Raw scores of caregiver assistance	17.1	17.0	18.8	17.8	15.3	16.3	0.40[b]

[a] Chi-square test.
[b] Student's *t* test.
Both the chronological age and the developmental age are one month.
DD = developmental delay; GDD = global developmental delay; MD = motor delay; SD = standard deviation; USD = United States dollars.

functional skills and caregiver assistance ($p = 0.39$ and 0.40, respectively). There were also no differences in the pre-test CDIIT between the two groups in cognition, language, gross, gross motor, fine motor, total motor, social and self-help ($p > 0.30$ for all analyses).

The performance comparisons between groups on the CDIIT and PEDI are summarized in Table 2 and Table 3, respectively. The developmental scores of the CDIIT increased significantly within groups and between groups. This result showed that after 12 weeks of rehabilitation, all children improved in the five developmental domains of the CDIIT when compared with developmental score between the pre-test and follow-up test (paired t test). On average, children in Group I reached a level of 2.11 months of developmental improvement, whereas children in Group II achieved 3.11 months of improvement. Comparison between groups based on the difference between the pre-test and follow-up test scores (T2 − T1) showed that children in Group II had greater improvement in cognition ($p = 0.02$), language ($p = 0.01$), motor ($p = 0.03$ for gross motor; $p = 0.00$ for fine motor) and social domains ($p = 0.04$) but not in the self-help domain ($p = 0.24$, ANCOVA $p = 0.224$). The covariant of T1 was fixed and showed the same result.

Table 2
Comparison of the mean differences in developmental age between the pre-test (T1) and follow-up test (T2) based on the comprehensive developmental Inventory for infants and toddlers-diagnostic test raw scores

Domains of CDIIT-D	T1		T2		Change (T2 − T1)		p	ANCOVA significance
	Mean	SD	Mean	SD	Mean	SD		
Cognition							0.015[b,*]	0.012[b,*]
Group I	13.9	7.0	16.7	8.0	2.78	2.14	0.00[a,*]	
Group II	12.8	6.5	16.9	6.7	4.10	2.30	0.00[a,*]	
Language							0.010[b,*]	0.010[b,*]
Group I	13.5	7.5	15.6	7.9	2.16	1.64	0.00[a,*]	
Group II	12.4	5.8	15.6	5.9	3.23	1.72	0.00[a,*]	
Gross motor							0.030[b,*]	0.015[b,*]
Group I	13.6	7.2	16.0	8.2	2.42	1.89	0.00[a,*]	
Group II	13.3	7.6	16.9	8.9	3.61	2.55	0.00[a,*]	
Fine motor							0.000[b,*]	0.000[b,*]
Group I	14.2	7.8	16.5	7.8	2.31	1.88	0.00[a,*]	
Group II	13.6	7.6	17.6	8.1	4.09	1.95	0.00[a,*]	
Motor total							0.000[b,*]	0.000[b,*]
Group I	13.8	7.3	16.2	7.8	2.37	1.24	0.00[a,*]	
Group II	13.2	7.2	17.0	8.3	3.80	1.89	0.00[a,*]	
Social							0.038[b,*]	0.026[b,*]
Group I	12.4	5.5	14.1	6.4	1.77	1.99	0.00[a,*]	
Group II	11.3	4.3	14.1	4.7	2.76	1.93	0.00[a,*]	
Self-help							0.239[b]	0.224[b]
Group I	13.3	7.0	15.7	7.8	2.37	2.37	0.00[a,*]	
Group II	11.9	5.9	14.9	5.9	2.96	1.68	0.00[a,*]	
Total score							0.000[b,*]	0.000[*,b]
Group I	13.0	6.4	15.1	6.9	2.11	1.18	0.00[a,*]	
Group II	12.0	5.4	15.1	5.5	3.13	1.01	0.00[a,*]	

[a] Paired t-test within groups for the pre-test and follow-up test.
[b] Comparison of the mean differences in developmental age between groups.
*A p value <0.05.
ANCOVA = analysis of covariance; CDIIT-D = comprehensive developmental Inventory for infants and toddlers-diagnostic test; T1 = pre-test; T2 = follow-up test.

Table 3
Comparison of the mean differences in PEDI scores between the pre-test (T1) and follow-up test (T2) based on the PEDI raw scores

PEDI domains	T1		T2		Change (T2 − T1)		p	ANCOVA significance
	Mean	SD	Mean	SD	Mean	SD		
Functional skills								
Self-care							0.000[b,*]	0.000[b,*]
Group I	14.29	10.73	17.43	11.42	3.14	1.59	0.00[a,*]	
Group II	12.29	9.79	17.11	10.24	4.83	2.15	0.00[a,*]	
Mobility							0.004[b,*]	0.007[b,*]
Group I	23.29	17.11	27.29	16.92	4.00	2.41	0.00[a,*]	
Group II	19.63	16.85	25.80	16.28	6.17	3.61	0.00[a,*]	
Social							0.000[b,*]	0.000[b,*]
Group I	13.37	8.50	16.06	9.08	2.69	1.73	0.00[a,*]	
Group II	12.06	7.84	16.77	8.41	4.71	2.28	0.00[a,*]	
Total score							0.00[b,*]	0.000[b,*]
Group I	50.94	35.07	60.77	35.99	9.83	4.79	0.00[a,*]	
Group II	43.97	33.55	59.69	33.82	15.71	6.73	0.00[a,*]	
Caregiver assistance								
Self-care							0.22[b]	0.098[b]
Group I	3.17	5.02	3.86	5.39	0.69	0.68	0.00[a,*]	
Group II	2.51	3.95	3.46	4.51	0.94	1.03	0.00[a,*]	
Mobility							0.015[b,*]	0.023[b,*]
Group I	12.49	10.93	14.03	10.85	1.54	1.48	0.00[a,*]	
Group II	10.26	10.76	12.74	10.47	2.49	1.69	0.00[a,*]	
Social							0.003[b,*]	0.004[b,*]
Group I	3.14	3.09	3.89	3.13	0.74	0.886	0.00[a,*]	
Group II	2.57	2.58	3.97	2.64	1.40	0.914	0.00[a,*]	
Total score							0.003[b,*]	0.003[b,*]
Group I	18.80	17.78	21.77	18.03	2.97	2.57	0.00[a,*]	
Group II	15.34	16.34	20.17	16.65	4.83	2.40	0.00[a,*]	

[a] Paired t test within groups for the pre-test and follow-up test.
[b] Comparison of the mean differences in developmental age between groups.
*A p value <0.05.
ANCOVA = analysis of covariance.

As shown in Table 3, after 12 weeks of treatment, PEDI total functional skills and caregiver assistance scores in both groups had improved. The between-groups comparison showed that the follow-up test scores were significantly higher than the pre-test scores in Group II except for the self-care follow-up test scores in caregiver assistance ($p = 0.22$, ANCOVA $p = 0.098$).

The relations between the pre-intervention score and the improvement were analyzed by multivariate linear regressions and summarized in Table 4. Children gender, developmental diagnosis, status of DD, parents' educational level, family income, parents' age, the age of children when recruited, and pre-test developmental scores of CDIIT and PEDI were used as multivariate independent factors. The entry and removal levels were 0.05 and 0.1, respectively. (model:stepwise) The factors which were significant ($p < 0.05$) were listed in Table 4. The result showed that group factor was significant in most of the test items.

The mean and standard deviation of execution scores for parents' age, education level and family income are summarized in Table 5. The mean execution score for Group II subjects was 80 (SD = 7.0). The independent t test showed that for the parents with higher education level (82.7,

Table 4
Prediction of improvement by pre-intervention scores and subject characteristics. The independent factors and coefficient are shown if they had significant influence in the improvement of test items

Improvement (T2 − T1)	Factor	Multivariate coefficient	p
CDIIT			
Cognition	Group	1.29 ± 0.52	0.015
	Status of DD	−1.09 ± 0.52	0.04
Language	Group	1.07 ± 0.40	0.01
Gross motor	Pre-Gross motor	0.11 ± 0.03	0.003
	Group	1.19 ± 0.48	0.016
	Status of DD	−1.14 ± 0.49	0.024
Fine motor	Group	1.78 ± 0.46	0.000
Motor total	Group	1.46 ± 0.34	0.000
	Pre-motor total	0.08 ± 0.03	0.002
	Status of DD	−0.82 ± 0.35	0.022
Social	Group	0.99 ± 0.45	0.03
	Developmental diagnosis	−1.38 ± 0.48	0.005
CDIIT total	Group	1.02 ± 0.25	0.000
	Developmental diagnosis	−0.85 ± 0.27	0.002
PEDI			
Functional skills			
Self-care	Group	1.73 ± 0.43	0.000
	Age when recruited	0.06 ± 0.02	0.013
	Developmental diagnosis	−1.09 ± 0.47	0.02
Mobility	Group	2.17 ± 0.73	0.004
Social	Group	2.03 ± 0.47	0.000
	Developmental diagnosis	−1.03 ± 0.51	0.046
Functional skills total	Group	5.89 ± 1.40	0.000
Caregiver assistance			
Self-care	Age when recruited	0.04 ± 0.01	0.000
Mobility	Group	0.94 ± 0.38	0.015
Social	Group	0.66 ± 0.22	0.003
Caregiver assistance total	Group	1.86 ± 0.59	0.003

CDIIT = comprehensive developmental inventory for infants and toddlers test; DD = developmental delay; PEDI = pediatric evaluation of disability inventory.

SD = 6.6) and higher family income (83.8, SD = 5.6), the execution score was higher ($p = 0.02$ and 0.01, respectively) than that for the parents with lower education level (76.7, SD = 6.3) and lower family income (77.1, SD = 7.1). The Pearson correlation between home rehabilitation execution scores and the progression of CDIIT and PEDI scores was also assessed. No significant correlation (correlation coefficient > 0.5) was found between these parameters. Furthermore, neither the education level of parents nor the family income influenced the progression of children's development (data not shown).

Table 5
Mean and standard deviation of the execution scores of parents' age, education level and family income

	n	Execution score (mean)	SD	p
Group II		80	7.0	
Parents' age				0.73
30 and under	11	80.2	8.7	
31 and over	24	81.2	6.3	
Family income				0.008**
<20000 USD	17	77.7	7.1	
>20000 USD	18	83.8	5.6	
Parents' education level				0.02*
<12 yr of education	11	76.7	6.3	
>12 yr of education	24	82.7	6.6	

*A p value <0.05.
**A p value <0.01.
SD = standard deviation; USD = United States dollar.

4. Discussion

Our results suggest that children diagnosed as DD who receive early intervention will show improvement in developmental domains such as cognition, language, motor, self-help and social functions. Except in the self-help domain, subjects who received further HAPs showed much greater improvement in cognition, language, motor, social and PEDI mobility and social development than children who received IT only. This is consistent with other reports about autism and cerebral palsy indicating that when families are involved in treatment programs, DD children improve in a wide range of areas. The cohort in our study excludes children with defined diagnosis, this maybe the reason why these children get significant improvement in their development after 12-week intervention.

Because the range of ages was between 6 and 48 months, the ANCOVA was used to see the effect of ages before recruitment. It showed that there was no influence of the pre-test ages in the progression of development, and HAPs was the major influence for developmental progression.

Functional therapy is based on the concept of practicing primary functional skills (e.g. grooming, dressing and climbing stairs) to achieve functional goals and provide opportunities for practice in functional settings. This approach offers a good basis for individualized planning and developing skills that are useful

Table 6
Home activity programs record sheet

Please answer the questions below using the following five−point scale:
5-Strongly agree, 4-Agree, 3-Undecided, 2-Disagree, 1-Strongly disagree
1. I understood what the therapist told me about my child's home activity program.
2. I kept the weekly schedule of the home activity program.
3. I spent enough time doing the home activity program.
4. I think I managed the home activity program very well.

for the children and their parents.[30] In pediatric rehabilitation, the traditional intervention theories are usually impairment-focused and based on hierarchical and neuromaturation of motor control, such as neurodevelopmental therapy.[31,32] They emphasize promoting movement efficiency and enhancing movement strategies to enhance participation in functional activities. In functionally based intervention, learning outcomes are considered by a process of self-organized interaction between the children, tasks and the learning environment which are based on the theory of dynamic systems theory.[33,34] Activity-focused motor intervention is one of the most mentioned functionally based approaches.[29] In this model, the therapists focus on activity-related goals based on motor learning strategy. Structured practice and repetition of functional actions were arranged to learn purposeful tasks. This kind of task-specific therapy was recently suggested to be used in routine neuromotor interventions.[35] The HAPs provide more opportunities for training and practicing the therapeutic goals at home. This might be the reason why children in our study who participated in HAPs show greater improvement.

Training frequency is important for motor progress.[36] However, it is still uncertain how often is necessary for children to practice and learn functions. This seems to be dependent on many factors, such as the severity of the disability, the task to be learned, the environment, the learning capacity of the child, and the method used. In our study, the 12-week intervention using a once-a-week treatment program was enough to produce developmental benefits. Institutional-based programs, either alone or in combination children with home activity programs, are helpful for these children.

The average execution rate in our study was 80 (SD = 7.0), which is higher than the rates in other studies. It has been estimated that the average level of family compliance is about 50%. High compliance occurred in the cases where the parents participated in a study and the families were familiar with the investigator.[14] We think this high compliance level maybe because the parents knew they were participating in a study. Few studies have discussed the correlation between parents' age and the home program execution rate. In this study, we showed that parents' age had no influence on the execution rate. In parallel with our results, Galil et al. reported that lower education level and lower socioeconomic status were associated with lower parental compliance.[37]

The results of studies about home activity programs and outcomes have been mixed. Some studies about DD in low-economic family, cerebral palsy and language disorders revealed that parental involvement helps children to achieve their goals.[14,38,39] However, one study claimed that HAPs are not an effective tool for improving treatment programs.[40] This controversy maybe owing to the different education levels and socioeconomic statuses of the participants in different studies. The association between home program execution rate and the progress of development is not clear. In our study, although the home program execution rate was higher in families with high education level and high socioeconomic status, there was no strong correlation between the home execution rate and children's developmental outcomes.

For assessing appropriate goals for therapy, the PEDI was used. By using this scale, therapists can design exercises and provide ideas that can help children reach the next developmental step in daily activities. In a study about cerebral palsy, the functional goal-directed therapy was shown to contribute to significant progress in the domains of self-care and mobility.[28] In our study, although all developmental scores improved when compared with baseline scores, there was no difference in children's level of progress between groups in the self-care domain in the CDIIT and the self-care of caregiver assistance in the PEDI. This result was similar to that in Ahl et al.'s report.[27] Ahl and colleagues reported that functional therapy for children with cerebral palsy did not contribute to improvements in self-care and social function at the level of caregiver assistance. They concluded that this might relate to the children's slow performance of tasks because of a lack of automatization, making it difficult for parents to withdraw support.

There are three limitations in our study. One limitation is that it is still not clear how long the intervention programs should be to be effective. Because of the national health insurance reimbursement policy, some therapeutic programs may lose government funding over time. Our result showed that an intervention program of at least 12 weeks can have positive effects. Whether these effects will last and whether a longer duration is necessary to help these children still need furthermore investigation. The other limitation is that the therapists who participated in the treatment and evaluation were not blinded to the groups. It could be argued that therapists may devote more attention to the home activity program groups while they are in contact with the parents for home activity program execution. The third limitation is that in this study, there were no true controls who received no therapy. Although natural improvement can be found in children with DD, literature about natural developmental improvement were difficult to find. Children diagnosed with DD was logically thought not to gain normal development by natural course. In Taiwan, the developmental screening and intervention programs were designed to find children with DD, and give them early intervention as early as possible. This is why we didn't design an observed control group.

In conclusion, although it is not known how much progress maybe accounted for by maturation alone over this three-month period, clinic-based institutional therapy with or without HAPs can both help children to have improvement in their development. The addition of a home activity program results in greater average functional progress than is seen with IT alone.

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