

TITLE: Collaborative Home-Visit Program for Young Children With Motor Delays in Rural Taiwan: A Pilot Randomized Controlled Trial

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AUTHOR BYLINE: Yu-Hsin Hsieh, Hua-Fang Liao, Suh-Fang Jeng, Mei-Hui Tseng, Veronica Schiariti, Mei-Yan Tsai, Sheh-Chia Sun

AUTHOR INFORMATION:

Y-H. Hsieh, PT, MSc, Department of Special Education, Stockholm University, Stockholm, Sweden.

H-F. Liao, PT, MSc, Academic Committee, Taiwan Society of ICF, 5th Floor, No. 166, Dayei Road, Baitou District, New Taipei City, Taiwan, and School and Graduate Institute of Physical Therapy, College of Medicine, National Taiwan University, Taipei, Taiwan. Address all correspondence to Professor Liao at: hfliao@ntu.edu.tw.

S-F. Jeng, PT, PhD, School and Graduate Institute of Physical Therapy, College of Medicine, National Taiwan University.

M-H. Tseng, ScD, School and Graduate Institute of Occupational Therapy, College of Medicine, National Taiwan University.

V. Schiariti, MD, PhD, MHSc, Division of Medical Sciences, University of Victoria, Victoria, British Columbia, Canada.

M-Y. Tsai, MSc, Taiwan Social Welfare Action Alliance, Taitung, Taiwan.

S-C. Sun, EdD, Department of Early Childhood Education, Teachers College, National Taitung University, Taitung County, Taiwan.

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Background. Caregiver engagement and collaborative team early childhood intervention (ECI) services are international trends; however, relevant evidence of the collaborative home-visiting ECI in rural areas is as yet undetermined.

Objective. The study aimed to investigate the effectiveness of a collaborative ECI program in a rural area of Taiwan.

Design. The study was a pilot randomized control trial.

Methods. Children aged 6 to 33 months experiencing motor delays and their caregivers were enrolled in Taitung, Taiwan. Using stratified randomization, 24 participants were allocated to either experimental or control groups, and both received 5 home visits within 3 months. The experimental group received ECI services based on the International Classification of Functioning, Disability and Health (ICF) framework and family-centered approaches. The control group received regular home visits by local social workers. Child outcomes included Pediatric Evaluation of Disability Inventory Chinese Version and Peabody Developmental Motor Scale, 2nd Edition. Family outcomes included the Disability-Adapted Infant–Toddler version of Home Observation for Measurement (DA-IT-HOME), and Chinese versions of the Knowledge of Infant Development Inventory, and Parental Stress Index-Short Form. A tester blinded to the study conducted assessments at baseline, post-intervention, and 3-month follow-up. Two-way mixed ANOVA was used with $\alpha = 0.05$ (2-tailed).

Results. The experimental group improved scores on the DA-IT-HOME significantly more than the control group with ES_f of 0.64 at follow-up. In other outcomes, both groups showed no significant differences. The follow-up rate was 69% and adherence to the ECI program was acceptable.

Limitations. A limitation of the study was the heterogeneity of the sample.

Conclusion. This pilot study revealed possible effectiveness in implementing collaborative ECI programs based on family-centered approaches and the ICF in rural areas. Larger field studies are needed to confirm our findings.

The prevalence rate of developmental delays and disabilities has been reported as 5% to 17% in children younger than 17 years.^{1,2} One Taiwan study demonstrated that one-third of such children had problems of motor delays.³ Therefore, we estimate the prevalence rate of motor delays to be approximately 1.7% to 5.7%. Many children with motor delays have sensory and cognitive impairments as well, which further affect their participation in age-appropriate activities of daily living.^{4,5} Based on the developmental systems approach⁶ and the International Classification of Functioning, Disability and Health (ICF) framework,^{7,8} activities and participation in children with motor delays are influenced by their physical and psychological functioning as well as environmental and personal factors. As such, home environments are critically important for young children with motor delays.

Nowadays, activities and participation are viewed as the optimal goal of early childhood intervention (ECI),⁹ and timely identification of children with disability or developmental delays will enhance participation if the environment has appropriate responses to individual needs, especially a better home environment¹⁰; therefore, Taiwan has pioneered in adopting the ICF biopsychosocial approach for planning service provision at a national level since 2007.^{9, 11-13} With the paradigm shift of emphasizing parent participation in the ECI, and following the social welfare system, the National Health Insurance Administration in Taiwan has encouraged family-centered ECI services provided by professionals in medical settings since 2013.¹⁴ The Protection of Children and Youth Welfare and Rights Act in Taiwan also specifies that an individualized family service plan should be provided for children with developmental delays,¹⁵ and family outcomes are as important as children's outcomes.^{14,16} Therefore, ECI must be individualized, flexible, responsive to family circumstances, and involve family members in acting on choices to strengthen child,

parent, and family capacities.^{6,17-20} Physical therapists using family-professional collaboration approaches to address family needs and to engage families in the ECI process could lead to more parent satisfaction and confidence.¹⁷ Moreover, the ICF provides a comprehensive guide for physical therapists for considering functioning and environmental factors as part of ECI services.²¹ However, more evidence is needed to support the implementation of family-centered and ICF-based ECI services in different contexts in Taiwan; particularly, the family-centered ECI delivered by a collaborative team at home.

In Taiwan, ECI resources are insufficient in rural areas,²² particularly in Taitung County, one-tenth of the Taiwan region stretching over 176 kilometers longitudinally. The population consists of one-third aboriginals, and about 500 children aged 0 to 6 years are at risk of or with developmental delays, with 60% of those living outside urban areas. ECI services are mainly in Taitung city and transportation from rural areas to the city is inconvenient, resulting in ECI inaccessibility for children with developmental delays living outside the city. In rural areas, families experiencing poverty usually have several stressors interfering with parental capacity to provide a nurturing home environment for their children.²³ Home visiting might well serve as an important resource for facilitating access to ECI services,²⁴ with appropriate environmental interventions supporting children in achieving their full potential.¹⁰ For families with low socioeconomic status (SES), home-visiting programs address their needs to increase their sense of control and engagement in ECI practices.^{19,25} Many studies have investigated the outcomes of home-visiting programs for children in families of low SES or developmental delays²⁵⁻²⁷; however, more evidence is needed to determine beneficial effects of such programs on outcomes for both family and children with developmental delays.^{25,27-29}

Moreover, few studies have included children's participation outcomes.³⁰ To our best knowledge, no studies have examined home-visiting effects on both children's participation and parental outcomes in rural areas in children with motor delays.

Providing a home-visiting ECI service based on ICF and family-centered approaches in Taiwan's rural areas delivered by paraprofessionals having ECI training certification but not licensed as professionals might be a viable strategy to improve maternal and children's outcomes.³¹ Participation of paraprofessionals from the same communities would enhance trust and communication during ECI delivery and avoid cultural pitfalls of dispatching nonindigenous people into the home.^{23,25} However, paraprofessionals as direct service providers need professional support,³² and the effectiveness and acceptability of such programs need to be studied in Taiwan; consequently, this study introduced a university pediatric physical therapy program collaborating with a social welfare institute in a rural area to provide a collaborative home-visiting ECI in order to overcome under-resourced problems.

The purposes of this pilot randomized controlled trial were to investigate: whether the collaborative ECI show trends toward better outcomes in young children with motor delays and their families than regular care and the acceptability of the collaborative ECI in rural areas of Taiwan. Children's and families' outcomes included children's daily participation, children's motor capacity, quality of the home environment, parenting stress, and parental knowledge.

[H1]Methods

[H2]Participants

A convenience sample of families of children who were 6 to 33 months old and had motor delays were recruited from the Early Intervention Case Management

Center in Taitung County, Taiwan. The study was approved by the Human Subjects Review Committee at National Taiwan University Hospital, Taipei, Taiwan, in 2007.

Eligibility criteria for children were as follows: being younger than 3 years; having a diagnosis of motor delays or a developmental quotient on the motor domain of the Comprehensive Developmental Inventory for Infants and Toddlers of less than 85³³; fitting into neuromuscular Pattern B or C of the *Guide to Physical Therapist Practice*³⁴; and having main caregivers with at least a primary education level in order to answer the questionnaires and sign consent forms. Exclusion criteria included children having received botulinum toxin A (Botox; Allergan, Dublin, Ireland) or surgeries, an unstable medical condition (eg, severe heart disease), or progressive diseases.

[H2]Design

This study was a pilot randomized controlled trial with single-blind outcome assessment, referring to guidelines for pilot studies proposed by the National Institute for Health Research.³⁵ After indicating interest in participation, the enrolled children were stratified according to age (≥ 18 months or < 18 months) and motor severity (motor developmental quotient of the Comprehensive Developmental Inventory for Infants and Toddlers of ≥ 55 or < 55)^{29,36} with a block size of 4. Randomization was executed by drawing a sealed, opaque envelope containing assignment by a person who was not involved in and, therefore, was masked with regard to this study. The experimental group received the collaborative ECI services and the control group had regular home visits. Dependent variables were assessed at baseline, immediately after intervention, and at follow-up (3 months after intervention) by the same assessor who was masked with regard to group assignment and intervention procedures. Participant

allocation is outlined in Figure 1.

[H2]Procedure

[H3]Intervention dosage and content. Both experimental and control groups received 4 biweekly home visits in the first 2 months and a single home visit in the third month. Each home visit lasted 1 to 1.5 hours.

[H3]Collaborative early intervention. The team members included pediatric physical therapists from the university physical therapy program in Taipei City (as program designer and consultants), direct service providers (DSP, to provide home-visiting services), social workers (intake and providing family resources) and a local institute administrator in Taitung County. The collaborative ECI was based on the concepts of transdisciplinary and interdisciplinary approaches.³⁷ The physical therapists organized the intervention project and developed individualized service plans with local team members (social workers and DSP) based on the Patient/Client Management Model proposed by the American Physical Therapy Association,³⁴ ICF framework,⁸ and family-centered approach.²⁰

The DSP was either a local paraprofessional (58%) or physical therapist (42%) according to availability, accessibility, and affordability of the original local resources. The paraprofessionals had graduated from senior high school or above, had relevant experiences of early childhood care, and had acquired a special training course completion certificate of educational and care personnel for ECI (20 credits with 360 hours of training) according to the Regulations for Governing Qualifications and Trainings of Professional Personnel of Children and Youth Welfare Institutes.³⁸ They had average ECI experiences of 1 to 5 years and at least 18 hours of continuing ECI

education per year. The local therapists were licensed physical therapists with a bachelor's degree in physical therapy, majoring in pediatrics.

For each family, the collaborative ECI services included 4 steps. Step 1 was to determine family-identified needs and the child's functional goals. The university physical therapists organized ICF-related assessments and facilitated goal selections by the team using ICF framework.³⁹ Figure 2 presents measures related to activities and participation,^{33,40,41} body function and structures,⁴²⁻⁴⁵ environmental factors,⁴⁶⁻⁴⁸ and personal factors. Step 2 was to design the individualized family service plan with a top-down approach, where the participation status in his/her daily setting was the main focus,²¹ and 3 functional activities that referred to the Carolina Curriculum for Infants and Toddlers with Special Needs⁴⁹ merged with 8 to 10 functional goals of that child were established by the university physical therapist (the program designer). Step 3 was to implement home visiting. DSP instructed caregivers during the 5 home visits. The program designer jointly visited the home with DSP twice and online case meetings were held biweekly to ensure fidelity and quality of home visits. Step 4 was to monitor progress (Appendix).

To assess acceptability, we measured intervention completion rate, follow-up rate, adherence to, and helpfulness/satisfaction with the collaborate ECI. Intervention completion rate was defined as the number of children completing the 3-month intervention divided by the number of children at baseline. The follow-up rate was the number of children at follow-up divided by those at baseline. Adherence was measured by number of implementation times per week in recording logs wherein caregivers recorded the execution of functional activities. After the 3-month intervention, caregivers answered a study-designed questionnaire, with 5 helpfulness and 4 satisfaction items using a 5-point Likert scale, where 1 = not at all

helpful/satisfactory to 5 = extremely helpful/satisfactory. The helpfulness items asked about helpfulness of the intervention to the whole family, to child development, to parent-child interaction, to caregivers' understanding their child's abilities, and to decrease in parenting stress. The satisfaction items asked about the overall satisfaction, way of service delivery, quality of services, and fitting into family expectations. Helpfulness and satisfaction scores became the average score, ranging from 1 to 5, with higher scores indicating higher helpfulness and satisfaction as perceived by caregivers.

[H3]Regular home visiting. The control group received a regular home-visiting program by a local social worker, who integrated family history and current family situation, medical or social resources available, and analyzed the priority of needs for the child and family. The regular program included issues related to children's health and development, parenting skills, access to community services and social welfare resources, assistive devices, and emotional support for the family. If the priority of the family's concern was their child's development or medical resources, the social worker referred to related services outside the institute. Regular home-visit content did not refer to the ICF model. Table 1 lists the different elements in 2 groups.

[H2]Outcome Measures

Children and family measures were chosen as primary and secondary outcomes. The primary outcome measures were the Chinese version of the Pediatric Evaluation of Disability Inventory (PEDI-C), the Peabody Developmental Motor Scales–2nd Edition (PDMS-2), and the Disability-Adapted Infant-Toddler Version of Home Observation for Measurement (DA-IT-HOME). The secondary outcome measures

were the Chinese version of the Parental Stress Index–Short Form (PSI-SF-C) and the Chinese version of the Knowledge of Infant Development Inventory (KIDI-C).

Primary outcomes were assessed 3 times (before and after treatment and at follow-up), and secondary outcomes were assessed 2 times (before and after treatment).

[H3]Chinese version of the Pediatric Evaluation of Disability Inventory (PEDI-C). The PEDI-C was used to evaluate children’s activities and participation by a structured interview with the primary caregiver. The PEDI-C has been cross-culturally adapted and demonstrates good test-retest reliability (ICC = 0.98–1.00) and concurrent validity (Spearman rho = 0.92–0.99 with the Functional Independence Measure for Children).^{41,50} The PEDI-C has 3 domains (self-care, mobility, and social function) for children 0.5 to 7.5 years old. We used the scale scores in 3 domains of the Functional Skills Scale and the Caregiver Assistance Scale. The Functional Skills Scale measures the child’s capability, and the Caregiver Assistance Scale assesses the amount of assistance in daily functions. The minimal clinically important differences revealed 10.1, 8.7, and 13.9 points for the self-care, mobility, and social function domains of the Functional Skills Scale, respectively.⁵¹

[H3]Peabody Developmental Motor Scales–2nd Edition (PDMS-2). The PDMS-2 was used to evaluate children’s motor capacity and is a standardized, norm-referenced test for children 0 to 7 years old. It has gross motor and fine motor composites. The percentage scores of the total motor and 2 composites were calculated by summing the raw scores, dividing by the maximum raw score and then multiplying by 100.⁵² PDMS-2 showed good reliability (ICC = 0.73–0.96), internal consistency (Cronbach α = 0.96–0.97), appropriate construct validity with the 2-factor model,⁴⁰ and acceptable

standardized response mean (1.7–2.3).⁵²

[H3]Disability-Adapted Infant-Toddler Version of Home Observation for Measurement (DA-IT-HOME). The DA-IT-HOME was used to evaluate the quality of home environment for children with developmental delays.⁴⁶ It consists of 53 items and has 6 domains: responsiveness, acceptance, organization, learning materials, involvement, and variety. The DA-IT-HOME was administered by interviewing caregivers and observing the parent-child interaction and physical environment at home. Higher DA-IT-HOME scores indicate better quality of home environment. The internal consistency of the DA-IT-HOME was 0.49–0.76.⁴⁶ The Infant-Toddler Version of Home Observation for Measurement (IT-HOME) showed appropriate construct validity (5 factors). The responsiveness of the IT-HOME was acceptable as outcome measures.^{53,54}

[H3]Chinese Version of the Parental Stress Index–Short Form (PSI-SF-C). The PSI-SF-C was used to assess parenting stress.⁴⁷ The PSI-SF is a direct derivative of the PSI⁵⁵ and has a 36-item self-scoring questionnaire/profile with 3 subscales (parental distress, parent-child dysfunctional interaction, and difficult child). Higher scores represent higher levels of parenting stress. The PSI-SF showed acceptable test-retest reliability (ICC = 0.68–0.85), good internal-consistency (Cronbach α = 0.88–0.95), and appropriate construct validity (3 factors).⁵⁵

[H3]Chinese version of the Knowledge of Infant Development Inventory (KIDI-C). The KIDI-C was used to assess the knowledge of parents about typical infant development and health care.⁵⁶ It is a self-report questionnaire and consists of

75 items in 4 domains (norms and milestones, principles, parenting, and health and safety).⁵⁷ The KIDI showed adequate test-retest reliability (ICC = 0.80–0.92) and appropriate convergent validity with the Epstein Knowledge Scale ($r = 0.41$).⁵⁷ In this study, the total accuracy percentage score was used.⁵⁷

[H2]Data Analysis

We used SPSS 17.0 to conduct statistical analyses (SPSS, Inc, Chicago, IL, USA). For examining differences in baseline information between 2 groups, a chi-square test and an independent t test were used for nominal and continuous variables respectively. In further analysis, we used intention to treat by assigning the posttest scores as the follow-up scores for the dropped-out children in the manner of the study of Shyu et al.⁵⁸

A 2-way mixed analysis of variance with repeated measures was conducted to examine the main effects of groups, time (before intervention, immediately after intervention, and at follow-up), and group \times time interactions.⁵⁹ Cohen f was used to calculate effect sizes (ES_f) for all outcome variables between 2 groups. The ES_f values were interpreted as follows: small $ES_f = 0.10$, medium $ES_f = 0.25$, and large $ES_f = 0.40$.^{59,60} The alpha level was set at .05 (2-tailed) for all analyses. When the group \times time interactions were significant, repeated-measures analyses of variance were run for each group with a Tukey post hoc analysis.

[H2]Role of the Funding Source

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conduct, or reporting of this study.

[H1]Results

[H2]Recruitment and Sample Characteristics

A total of 26 families with children with motor delays were invited to participate, although disqualification criteria for 2 families meant only 24 were enrolled after signing consent forms. During the follow-up, 3 families in the experimental group and 2 families in the control group dropped out. Reasons included moving away ($n = 1$), family factors ($n = 2$), and families' opinions that follow-up was not necessary ($n = 2$) (Fig. 1).

There were no significant differences in the demographic data between the 2 groups at baseline (Tab. 2). Five children (42%) in 2 groups had the diagnosis of unspecified psychomotor delay. Other diagnoses in experimental and control groups included prematurity ($n = 1$ and $n = 2$, respectively), cerebral palsy ($n = 1$ and $n = 2$), chromosome disease ($n = 1$ and $n = 3$), torticollis ($n = 1$ and $n = 0$), ventricular septal defect ($n = 1$ and $n = 0$), Reye syndrome ($n = 1$ and $n = 0$), and hydrocephalus ($n = 1$ and $n = 0$). During the study, both groups continued to receive their original ECI services besides this study with the median of 6 times in the experimental group and 15 times in the control group.

Families' SES was classified based on 3 domains of employed status, educational attainment, and occupational prestige ranging from I to V, with V indicating the lowest level of SES.^{61,62} Most families in the experimental group belonged to class V (75%) (Tab. 2). The primary language was Mandarin Chinese, with some families having both Mandarin and Taiwanese, an aboriginal dialect, or other language. For marital status, 50% of the families in the experimental group had

parents who were married and living together compared to 75% of the families in the control group.

[H2]Acceptability of the Collaborative ECI

In the experimental group, 12 participants completed the 3-month intervention, with completion rate of 92%. Three dropped out during follow-up phase with the follow-up rate of 69%. According to the recording logs and verification during home visits by DSP, the functional activities were executed with an average rate of 39.8%, about 3 times per week. From the questionnaires, the average helpfulness score was 4.10 (SD = 0.51, range = 3.0–5.0) and satisfaction score 4.36 (SD = 0.48; range = 3.3–5.0). From field observations, children and families appeared highly engaged during home visits, and most children showed improvements after 2 visits.

[H2]Effects on Children

The mean scores on the PEDI-C, PDMS-2, DA-IT-HOME, KIDI-C, and PSI-SF-C showed no significant group differences at baseline ($P > .05$) (Tab. 3).

For all domains of the PEDI-C and PDMS-2, a significant time main effect was found; however, there was no significant time \times group interaction in these 2 outcomes ($P > .05$).

In further analysis, the PEDI-C change score in the experimental group was 11.4 immediately after intervention; this score was higher than the minimal clinically important difference on the Functional Skills Scale of the mobility domain in the PEDI-C, which was 8.7.⁵¹ In the control group, the change score on the Functional Skills Scale of the mobility domain in the PEDI-C was 7.7 immediately after intervention. The short-term and long-term ES_f values on the Functional Skills Scale

of the mobility domain were 0.53 and 0.28, respectively; these values represented large and medium effect sizes, respectively.

[H2]Effects on Families

There was a significant group \times time interaction effect ($F_{1,22} = 9.1$; $P < .0001$) for the DA-IT-HOME, the experimental group improved more than the control group (Fig. 3). The short-term and long-term ES_f values were 0.88 and 0.64, respectively, representing large effect sizes.

For parenting stress and parental knowledge, the mean changes in scores on the PSI-SF-C and KIDI-C did not show significant interaction effects ($P > .05$). However, the experimental group had trends of lower scores on the PSI-SF-C than did the control group. The ES_f was 0.47, representing a large effect size.

[H1]Discussion

This is the first pilot study to examine the effectiveness of a collaborative ECI services program for children with motor delays and their families in a rural area of Taiwan. The complexity of the intervention required a determination to ensure recruitment, randomization, intervention, and follow-up assessments could all run smoothly. Due to the small sample size, intervention effects could not be conclusively determined. Structural and organizational aspects such as randomization, masking, delivery of the intervention, retention of participants and analysis appeared feasible.

The preliminary results demonstrated significantly better change scores of quality of the home environment in the experimental group vis-à-vis the control group. Nonetheless, the group \times time effects were not statistically significant in children's daily participation and motor capacity, parenting stress and parental knowledge.

However, the experimental group had trends of lower parenting stress than did the control group. The change score of children's mobility participation in the experimental group was higher than the minimal clinically important difference, but not in the control group. Therefore, evidence of effectiveness to implement family-centered and ICF-based collaborative ECI in rural areas with paraprofessionals as DSP was partially supported.

Regarding acceptability, 92% participants in the experimental group completed the 3-month intervention with high helpfulness and satisfaction scores. The follow-up rate was 69%, compared to 46% to 86% in previous research,^{31,32,54} demonstrating that this novel ECI might be acceptable in rural areas in Taiwan. In the control group, intervention completion and follow-up rates were 100% and 83.3% respectively, indicating ECI programs in rural areas of Taiwan were acceptable. This study showed insufficient daily adherence in rural areas where the average home program implementation was only 3 times per week. Reasons of insufficient daily adherence might be the economic challenges of the region and grandparents being main caregivers. Future interventions could consider content modification to be more accessible and affordable for caregivers.

According to a UNICEF report, there is a disadvantaged link between poverty and disability.¹⁰ However, a family with poverty does not necessary have poor quality of home environment.⁶³ The families in this study had low educational level and low SES mostly, scores on the baseline DA-IT-HOME ranged from 28 to 52, with a mean of 40, which approximated to the median score of 39 in normative samples of Western countries.⁴⁶ In this collaborative ECI program, DSPs embedded instructions within and across routines and empowered caregivers while providing contextually relevant learning opportunities in the child's daily living.^{17,24,64} Family benefits were partially

dependent on how engaged and involved parents were in each interaction with both their child and the DSP.⁶⁵ Thus, this collaborative ECI demonstrated positive family outcome.

In this pilot study, interaction effects were not statistically significant in children's daily functioning and motor capacity, although the change scores for the mobility domain of the PEDI-C showed better improvement tendency in the experimental group than in the control group. The collaborative team set goals with parents, used home facilitators and overcame barriers based on ICF analysis to improve both children and caregivers' participation at home that might lead to increased child engagement and participation in mobility activities.^{30,66-69} However, due to small sample sizes, the findings should be considered cautiously. From the statistical results of this pilot study, the effect size for the mobility domain of the PEDI-C ($ES_f = 0.28$), and a power of 0.8, a larger sample size with at least 75 participants would be necessary to reach significance in the long-term effect.

Parenting stress and parental knowledge, however, showed no significant interaction effects. Nevertheless, compared with the control group, the experimental group showed a positive trend of stress alleviation with a large effect size. This might be due to parenting skills and consultation provided by the collaborative ECI that increased children's daily functioning as well as parental competence, further reducing parenting stress. Previous studies have also shown that caregivers' competence and children's abilities were significant contributors to parenting stress,⁷⁰ and parental knowledge was associated with education level of parents and income.⁷¹ In rural areas, parents might need longer intervention to increase parental knowledge significantly.

The unique characteristic of this collaborative ECI program was the role of

physical therapists as the program designer, who played an indirect and supportive role in a multidisciplinary team compared to a traditional physical therapist's role. Concerning the cultural differences and family needs in rural areas, DSPs were chosen from local paraprofessionals or local physical therapists in Taitung who were sensitive to cultural and socioeconomic diversity in the communities. This study showed applicable and acceptable team collaboration by joint home visiting twice and regular distance meeting, which could provide a reference for further tele-rehabilitation in rural areas in Taiwan. Due to the small sample size of this study, we did not examine the statistical differences of outcomes between the 2 experimental subgroups (paraprofessional and professional DSP). A quick glance at the data revealed no obvious differences between these 2 subgroups.

[H2]Limitations

There were some limitations in this study. First, the heterogeneity of children with or at risk for motor delays resulted in large within-group variation. A well-designed larger randomized control trial would likely reduce this bias. Second, the DSPs included both paraprofessionals and professionals with different ECI experience and training. Their varying competence might have influenced the outcomes. Specific preintervention training, case meeting, and supervision by professionals during intervention are recommended for fidelity of implementation.^{23,25,32,72,73} Third, we imputed postassessment values as follow-up values for missing data in both groups that might have led to biased parameter estimates.^{74,75} Although differences of the outcome variables between the complete data and incomplete data were not significant (all P s > .05), we explained the results with caution.

[H2]Conclusion

In summary, this pilot study provides evidence to support the possible effectiveness of ICF-based and family-centered collaborative home-visiting programs for young children with motor delays in a rural area in Taiwan. These results might provide a preliminary scientific basis for future national programs in Taiwan as well as help stakeholders in legitimizing early childhood investments.

Author Contributions and Acknowledgments

Concept/idea/research design: Y-H. Hsieh, H-F. Liao, V. Schiariti, S-C. Sun

Writing: Y-H. Hsieh, H-F. Liao, V. Schiariti

Data collection: Y-H. Hsieh, S-C. Sun

Data analysis: Y-H. Hsieh, H-F. Liao, S-F. Jeng, S-C. Sun

Project management: Y-H. Hsieh, H-F. Liao

Fund procurement: H-F. Liao

Providing facilities/equipment: H-F. Liao, M-H. Tseng, M-Y. Tsai

Providing institutional liaisons: M-Y. Tsai

Consultation (including review of manuscript before submitting): H-F. Liao, S-F.

Jeng, M-H. Tseng, V. Schiariti, S-C. Sun

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Ethics Approval

This study was approved by the Human Subjects Review Committee (Ethics Committee) at National Taiwan University Hospital, Taipei, Taiwan (ID 200701022R).

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Clinical Trial Registration

This trial was not registered in a trial registry as it began enrollment in 2007, prior to PTJ's adoption of the prospective trial registration requirement; therefore, the editor in chief waived the prospective trial registration requirement.

Disclosures

The authors completed the ICMJE Form for Disclosure of Potential Conflicts of Interest and reported no conflicts of interest.

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Table 1.
Comparison of the Features and Procedures of 2 Home-Visiting Groups^a

Parameter	Experimental Group	Control Group
Program characteristics	Family-centered and ICF-based collaborative intervention (structured)	Family-oriented consultation (nonstructured)
Interventionists for each family	Collaborative team: program designer, social worker, home-visiting DSP (1 paraprofessional or physical therapist), caregiver Team support: telemeetings biweekly and joint home visits twice	Multidisciplinary team Home-visiting DSP was 1 social worker ECI was provided by other professionals in medical settings without goal integration
Goal setting and planning	Children's and family's goals were determined by family, DSP, and team together Identified constraint factors and strength related to functioning and participation based on the ICF Team collaborated with family to design intervention strategies DSP instructed parents to facilitate children's functioning and participation	DSP discussed with parents and then identified goals Supported family needs Provided suggestions and referred to available resources
Intervention	Family support Strategies were embedded in daily routine Home affordances were provided	Family support Suggestions for children's health and development were provided

^aDSP = direct service provider; ECI = early childhood intervention; ICF = International Classification of Functioning, Disability and Health.

Table 2.
Basic Data for Children and Families in Experimental and Control Groups^a

Variable	Experimental Group (n = 12)					Control Group (n = 12)				
	No.	%	Mean	SD	Range	No.	%	Mean	SD	Range
Family ^b										
Main caregiver										
Parents	7	58				10	83			
Grandparents	5	42				2	17			
Age of main caregiver, y			39.5	14.6	24–73			36.5	13.1	18–63
Education of main caregiver										
> High school	0	0				3	25			
High school	5	42				5	42			
Junior high school	3	25				3	25			
Elementary school	4	33				1	8			
Socioeconomic status										
Class II	0	0				2	17			
Class III	0	0				0	0			
Class IV	3	25				6	50			
Class V	9	75				4	33			
Child ^b										
Age, mo			19.9	6.4	9–30			20.9	9.9	8–32
No. (%) boys	9	75				10	83			
ECI sessions in study period			6 ^c		0–49			15 ^c		0–50

CDIIT motor DA, mo			11.6	5.5	3.1–19.9			12.3	6.4	3.3–19.6
CDIIT motor DQ			47.1	26.5	1–84			51.3	27.8	1–81
CDIIT cognition DQ			63.2	20.2	11–83			62.8	20.7	12–86
Standard score for PEDI-C functional skills										
Mobility domain			31.5	15.2	9.7–53.9			34.3	8.5	17.8–45
Self-care domain			24.5	13.9	9–52			30.5	14.3	9.4–53.8
Social function domain			15.8	14.6	2.7–45.4			21.8	14.2	2.7–48

^aCDIIT = Comprehensive Developmental Inventory for Infants and Toddlers; DA = developmental age; DQ = developmental quotient; ECI = early childhood intervention; PEDI-C = Chinese version of the Pediatric Evaluation of Disability Inventory.

^bChi-square or independent *t* test revealed no significant differences, with a *P* value of >.05 between 2 groups for all variables.

^cMedian.

Table 3.
Comparisons of Outcome Measures Between Experimental and Control Groups^a

Outcome	Time of Assessment	Experimental Group (n = 12)		Control Group (n = 12)		$F_{1,22} (P)^b$ for:			Short-Term Cohen f	Long-term Cohen f
		Mean	SD	Mean	SD	Time × Group	Time × Group	Group		
PEDI-C ^c functional skills										
Self-care	Before	33.7	7.3	33.4	10.0	0.5 (.60)	62.2 (.00) ^d	0.0 (.96)	0.11	0.14
	After	38.8	6.7	37.8	10.7					
	Follow-up ^e	40.8	8.2	41.0	11.2					
Mobility	Before	38.2	18.8	40.7	23.8	1.7 (.22)	92.3 (.00) ^d	0.0 (.94)	0.53	0.28
	After	49.6	19.9	48.4	21.1					
	Follow-up ^e	52.4	19.8	53.3	20.4					
Social function	Before	26.0	12.8	26.5	14.9	0.4 (.70)	43.0 (.00) ^d	0.0 (.96)	0.11	0.13
	After	33.3	10.9	32.5	14.3					
	Follow-up ^e	36.4	10.1	37.6	13.2					
PEDI-C ^c caregiver assistance										
Self-care	Before	6.5	11.2	7.5	11.1	0.6 (.48)	11.3 (.00)	0.2 (.66)	0.06	0.17

							<i>d</i>			
	After	12.6	16.2	14.6	16.7					
	Follow-up ^e	12.9	16.7	17.8	19.1					
Mobility	Before	28.2	22.1	32.7	26.6	0.3 (.64)	17.3 (.00) <i>d</i>	0.2 (.70)	0.12	0.12
	After	38.5	27.0	40.4	23.3					
	Follow-up ^e	40.3	26.3	45.6	19.7					
Social function	Before	8.4	11.8	12.8	16.0	0.9 (.42)	4.2 (.02) <i>f</i>	1.1 (.32)	0.29	0.20
	After	9.7	12.9	17.3	16.6					
	Follow-up ^e	10.7	13.5	17.2	18.6					
PDMS-2 ^g										
Gross motor	Before	47.5	20.6	50.7	22.4	1.0 (.36)	49.3 (.00) <i>d</i>	0.1 (.80)	0.27	0.21
	After	56.3	21.8	56.6	21.0					
	Follow-up ^e	58.9	22.3	61.8	20.6					
Fine motor	Before	55.9	22.9	58.0	23.8	0.5 (.62)	64.4 (.00) <i>d</i>	0.0 (.94)	0.20	0.15
	After	65.5	20.3	65.6	21.8					
	Follow-up ^e	69.3	21.3	69.5	21.6					
Total motor	Before	51.4	21.1	54.1	22.8	1.0 (.36)	93.1 (.00)	0.0 (.86)	0.34	0.21

							<i>d</i>			
	After	60.5	20.6	60.7	21.2					
	Follow-up ^e	63.7	21.5	65.3	20.7					
DA-IT-HOME ^h	Before	38.1	6.1	42.0	6.2	9.1 (.00) ^d	15.2 (.00) ^d	0.0 (.86)	0.88	0.64
	After	44.5	4.1	42.0	5.2					
	Follow-up ^e	44.3	4.3	43.9	4.2					
KIDI-C ^g	Before	46.6	11.0	52.6	13.8	0.1 (.38)	6.7 (.04) ^d	0.2 (.34)	0.03	-
	After	49.0	11.0	53.7	8.3					
PSI-SF-C ^h	Before	72.6	18.6	63.3	18.2	4.1 (.06)	2.3 (.14)	0.0 (.88)	0.47	-
	After	66.3	13.7	67.7	12.5					

^aDA-IT-HOME = Disability-Adapted Infant-Toddler Version of Home Observation for Measurement; KIDI-C = Chinese version of the Knowledge of Infant Development Inventory; PDMS-2 = Peabody Developmental Motor Scales–2nd Edition; PEDI-C = Chinese version of the Pediatric Evaluation of Disability Inventory; PSI-SF-C = Chinese version of the Parental Stress Index–Short Form.

^b*F* and *P* values (2-tailed) were from 2-way mixed analyses of variance.

^cMean and SD are scaled scores.

^d*P* < .01.

^eUsing intention to treat to calculate the scores.

^f*P* < .05.

^gMean and SD are percentage scores.

^hMean and SD are raw scores.

Figure 1.

Flow chart of participants' enrollment, randomization, and data collection. CDIIT = Comprehensive Developmental Inventory for Infants and Toddlers; DQ = developmental quotient.

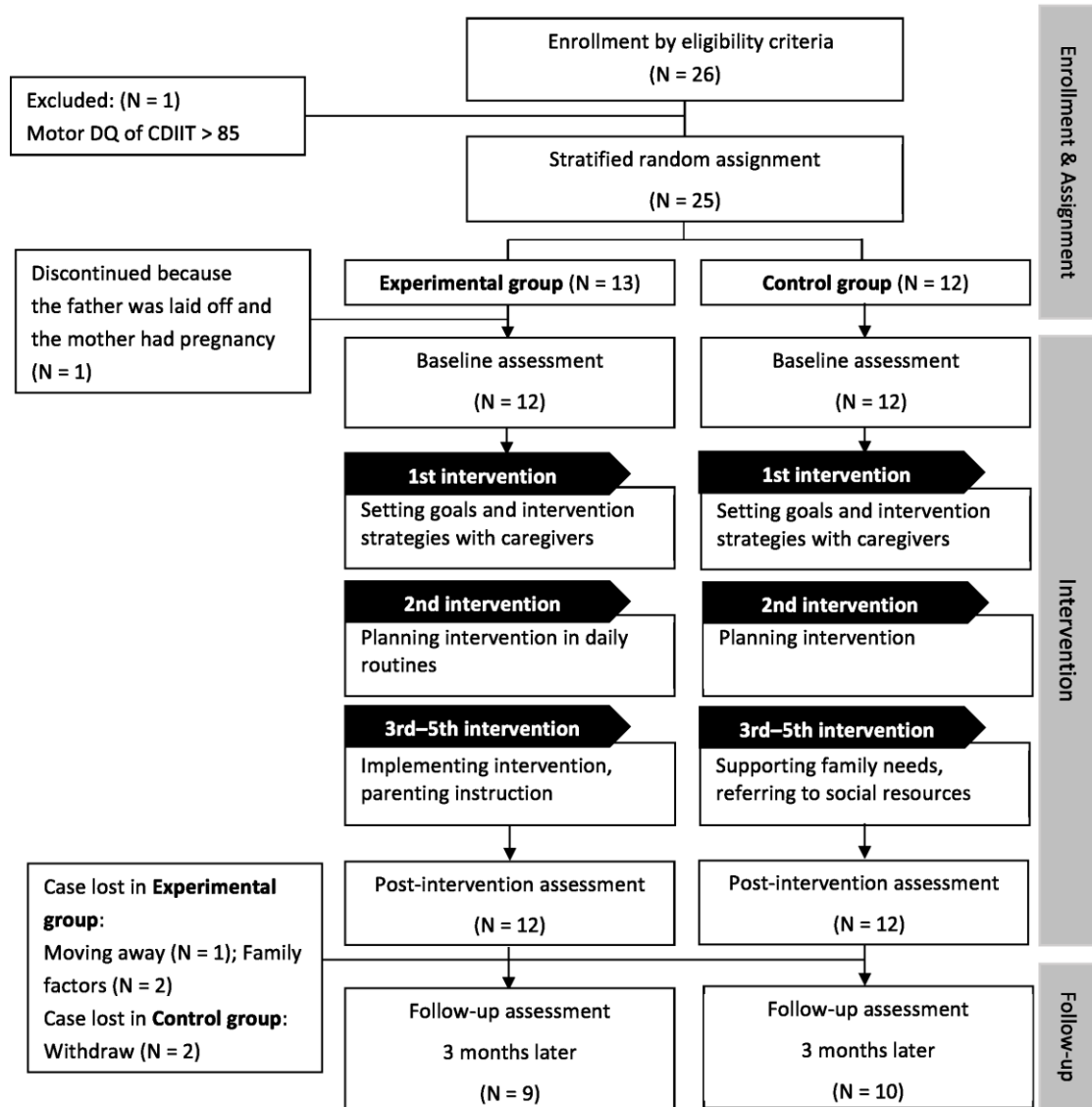


Figure 2.

International Classification of Functioning, Disability and Health–related measures used in this study. AHEMD-C = Affordances in the Home Environment for Motor Development–Chinese version; CDIIT = Comprehensive Developmental Inventory for Infants and Toddlers; DA-IT-HOME = Disability-Adapted Infant-Toddler Version of Home Observation for Measurement; DMQ = Dimensions of Mastery Questionnaire; KIDI-C = Chinese version of the Knowledge of Infant Development Inventory; PBS = Pediatric Balance Scale; PDMS-2 = Peabody Developmental Motor Scales–2nd Edition; PEDI-C = Chinese version of the Pediatric Evaluation of Disability Inventory; PSI-SF-C = Chinese version of the Parental Stress Index–Short Form; ROM = range of motion.

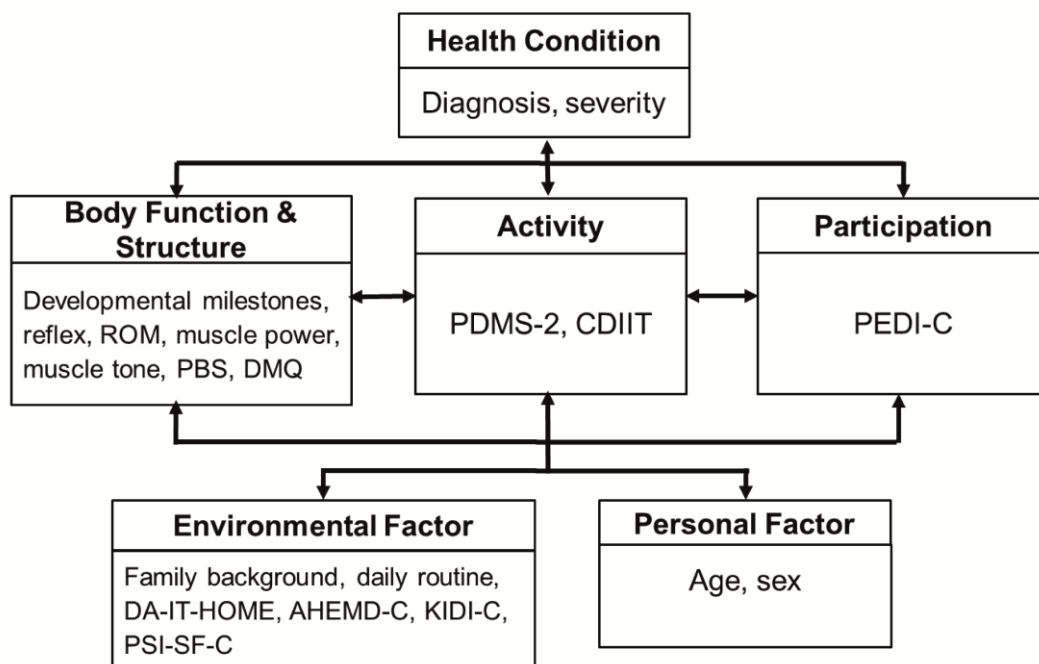
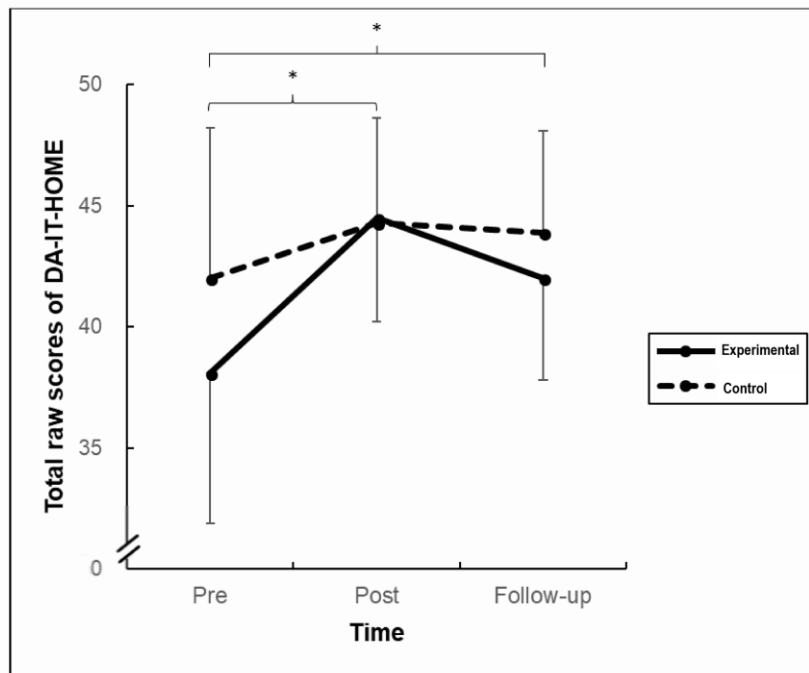
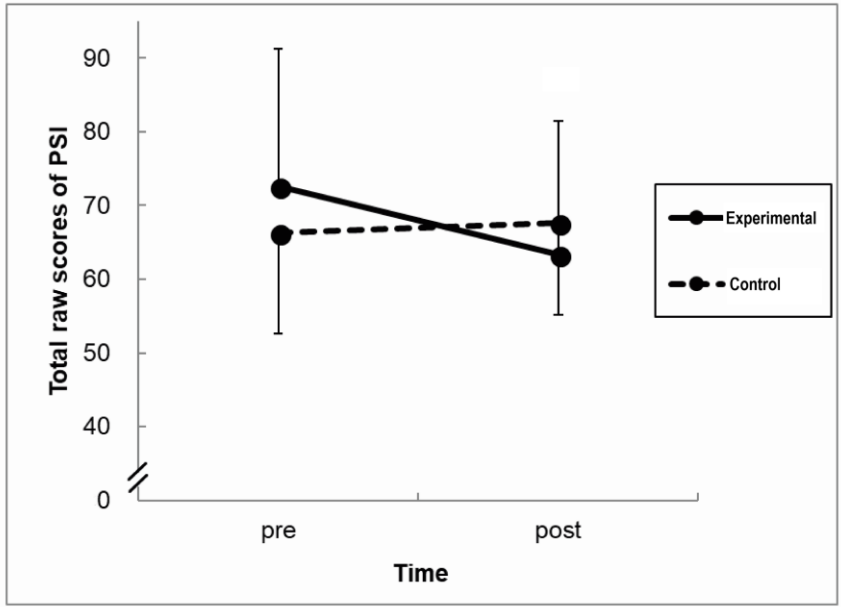


Figure 3.

Group \times time interaction effect of the Disability-Adapted Infant-Toddler version of Home Observation for Measurement (a) and the Chinese version of the Parental Stress Index–Short Form (PSI-SF-C) (b).





Appendix.

Four Steps of Collaborative Early Intervention Based on the International Classification of Functioning, Disability and Health (ICF) Framework and Family-Centered Approaches in Rural Areas of Taiwan

Step 1. Determine family-identified needs and the child's functional goals

The collaborative team collected information of the parents' major concerns, family needs, child's functioning, and environmental facilitators / barriers to set important, feasible and achievable goals of the individualized service plan for 3 months. Mutually agreed-upon goals usually contained 8 to 10 children's functional goals and 3 to 5 family goals for each child and family. Family goals included strengthening parenting knowledge and skills, parenting competence and empowerment, and adaptation of the home environment to increase children's participation.

Before goal setting, the ICF-related assessment was conducted to demonstrate the whole picture of each child and his/her family. The university physical therapists organized and analyzed this information to identify relationships among components of functioning and contextual factors that facilitated goal selections by the team.³⁹ The measures included the following (Fig. 2). For activities and participation, the Peabody Developmental Motor Scales–2nd Edition,⁴⁰ the Chinese version of the Pediatric Evaluation of Disability Inventory,⁴¹ and the Comprehensive Developmental Inventory for Infants and Toddlers³³ were used. For body function and structures, muscle power,⁴² muscle tone,⁴³ range of motion,⁴³ the Pediatric Balance Scale,⁴⁴ developmental milestones, and the Dimensions of Mastery Questionnaire⁴⁵ were used. For environmental factors, the measures used were the Disability-Adapted Infant-Toddler version of Home Observation for Measurement⁴⁶; the Chinese version

of the Parenting Stress Index–Short Form⁴⁷; a daily routine and activity interview; Affordances in the Home Environment for Motor Development Self-Report⁴⁸; family background; and the frequency, starting date, and content of the original ECI in the clinic. For personal factors, age, sex, and race were used. For health condition, diagnosis was used.

Step 2. Design individualized family service plan

The ICF framework serves to organize decision making into 3 broad levels—participation, activities, and body function and structures—while providing for the consideration of personal and environmental factors that would certainly affect child outcomes. With a top-down approach, the level of participation was the main focus and informed the team how a child functions in his/her daily setting. Before home visiting, 3 functional activities that referred to the Carolina Curriculum for Infants and Toddlers with Special Needs⁴⁹ and merged with 8 to 10 functional goals of that child were established by the program designer (the university physical therapist). Each activity included the goals, materials, location, procedure, functional activities fitting into daily routines, the expected standard of each activity, the practice time of each activity, and the environmental adaptations for children with special needs.

Step 3. Implement home visiting

The direct service provider (DSP) instructed caregivers during 5 home visits. The program designer joined home visiting with DSP twice and on-line case meetings biweekly to ensure fidelity and quality of home-visits. The DSP, or program designer sometimes, and main caregivers worked together while implementing the intervention and modified the intervention plan if the child made progress or other family's needs

were found. The caregivers were invited to share observations including changes in the child's performance, successful experiences and challenges between sessions, and discussed with DSP how activities might be progressed, or how possible solutions and the intervention plan could be modified accordingly if unexpected issues occurred.

The DSP instructed caregivers about child's developmental knowledge, and parenting skills such as monitoring developmental behaviors of the child, positive and appropriate interactive behaviors with the child (providing children with choices, praising, and encouraging the child's efforts) and appropriate support to participation in daily living. For example, for achieving functional walking goals, the DSP discussed with parents what equipment was available at home such as pull toys or scooters to facilitate walking of the child. The environmental support and materials adaptation were discussed with the family, for examples, re-arranging the furniture and corners to facilitate movement or play; adapting toys and utensils by increasing stability, making them larger or easier to be used.

Step 4. Monitor progress

A recording log was used for caregivers to document the execution of functional activities in daily routine for collecting the adherence and related information during the intervention period. The DSP discussed the recordings with parents/caregivers during each home visit, and also discussed the subsequent intervention activities based on the results of shared evaluation, family needs and routines. The following activities may be revised by increasing frequencies embedded in different routines, increasing difficulty level (for example, walking in various ground surfaces, dressing with less assistance), increasing engagement duration, or increasing complexity of context (such as from walk alone to walk and play ball activities with siblings).