Effectiveness of the Caregiver-Mediated Intervention: A Pilot Study for Children with Neurodevelopmental Disorders

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Abstract

Background: The Caregiver-Mediated Intervention(CMI), based on Parent Skills Training(PST), is one family-mediated intervention model for children with neurodevelopmental disorders(NDDs), especially for ASD. This study aims to evaluate the effectiveness of CMI.

Methods: 33 children (aged 22-69 months from our department) and their caregivers were included in a two-week training of ten 90-minute lessons. Then caregivers were encouraged to try their best to apply intervention skills in both home routines and play routines, in order to prompt the ability of cognition, motion, social adaptability and behavior of children. The based demographic information, video-taking data and diagnostic sales were collected at two key time-points at least: Baseline(BL); Post-training (PT; within six months).

Results: The outcomes mainly involved three aspects - primary variables, secondary variables and correlation analyses. Compared with BL, those favored PT in (1) Adult/Child Interaction Fidelity Rating ($P<0.01$), (2) adaptability of Gesell Developmental Scale and stereotyped behaviors and limited interests of Autism Diagnostic Observation Schedule ($P<0.05$, $P<0.01$). Moreover, a negative correlation appeared between caregiver skill improvement and parent education($P<0.05$), without correlation with other demographics.

Conclusions: As an efficacious family intervention for both children and their caregivers, CMI, with little limitation, is worth being generalized widely.

Trial registration: China Clinical Trial Registry (ChiCTR-IOC-17013638, 15/12/2017).

Background

Neurodevelopmental disorders (NDDs) in children are a class of chronic developmental cerebral dysfunction caused by complex genetic and environmental factors, which affect the cerebrum function areas of cognition, motion, social adaptability and behavior, such as autism spectrum disorders(ASD), global developmental delay(GDD), intellectual disability(ID), attention deficit hyperactivity disorder(ADHD) and so on(1, 2). With an increasing morbidity year by year, it's reported that the morbidity of NDDs in Taiwan has risen from less than 1.3% in the early 1990s to nearly 3% in 2016(3). With no specific therapeutic schemes, ASD and GDD, as the representative diseases, emphasize the principle of lifelong intervention, meaning heavy burden for all, which requires a long intervention period and the joint efforts of hospitals, families, educational institutions and communities. Because children with NDDs have a close contact with family caregivers for day and night, family-mediated intervention models certainly matter. Compared with multitudinous intervention of models, targets and assessments in ASD abroad, however, systematic and scientific family-mediated intervention models are still lacking in China(4). China has a large population of children with ASD, which leads to intervention resources relatively inadequate.

Under the circumstances, family-mediated intervention models, as low-intensity interventions(5), are relatively low in cost and adaptable for the clinic or home and for groups or individuals(6). In 2008, WHO launched the Mental Health Gap Action Program (mhGAP) to facilitate the achievement of targets of the Comprehensive Mental Health Action Plan 2013-2020. The original intention of mhGAP was to help people with mental, neurological and substance use (MNS) disorders by reinforcing the commitment of governments, international organizations and other stakeholders to increase the apportion of financial and human resources, and especially by improving the coverage with key interventions in low- and middle-income countries. In 2010, mhGAP-Intervention Guide (mhGAP-IG), version 1.0, was released and translated into several official languages of the United Nation to provide evidence-based guidance for all WHO regions. In 2015, mhGAP-IG, version 2.0, was the revise of the previous one. In the guidance, Parent Skills Training (PST) (7)was recommended to be a key intervention strategy for caregivers of children with developmental disorders/delays aged 2 to 9 years to improve the caregiver/child relationship, promote child's functioning and developmental outcomes and sustain caregiver's role and functioning. The research in Pakistan(7), as one of the three RCTs, follows a cascade model. First, the master trainers will train 10 trainers through 10-day class-room trainings. Then the trainers will provide guidance for "champion" family volunteers who are caregivers of children

with developmental disorders/delays for at-least 6 months duration of the program, and at last the volunteers will cascade the training consisting of nine weekly sessions to 4–5 families in their villages.

In view of the current medical and health situation in China, the number of patients with NDDs requiring intervention is massive, and at the same time access to family intervention through community is still not available. This study was designed to analyze the intervention effectiveness of the Caregiver-Mediated Intervention(CMI) base on PST in order to provide some evidence for domestic family intervention model.

Methods

Inclusion Criteria

All children, with no severe acute or chronic diseases, need meet the diagnostic criteria for ASD or GDD of the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition(DSM-5) and clinical judgment by physician with complete related diagnostic test scale results before the training, aging from 18 to 72 months without systematic trainings. The caregivers should sign the informed consent of the course and video recording, uploading at least two videos at two key time-points: Baseline(BL) and Post-training (PT; within six months), presenting the interaction about home routines or play routines, with about 10 minutes every video.

Participants and Ethical Considerations

33 children and their caregivers, who participated CMI course in the Department of Child Health Care of our hospital from September 2018 to June 2019, met the inclusion criteria and were enrolled, with 30 boys and 3 girls. The age ranged from 22 to 69 months and the mean age was 39.61 ± 13.12 months. The Institutional Research Ethics Boards approved the study and caregivers gave informed consent to participate. 31 children confirmed as ASD and 2 GDD. Caregivers filled in information when participating CMI. Table 1 showed the family characteristics including residence, main caregiver, family structure, parental education and annual household income.

Procedure

CMI is based on the theory of Applied Behavior Analysis(ABA), mainly for children aged 2-6 years with NDDs and their caregivers who haven't trained before systematically. CMI consisted of ten 90-minute sessions, 2 weeks a teaching cycle, and it was carried out by qualified trainers of our department who were trained and supervised by the master trainer of PST through the standard training videos. Parent-theory teaching and parent-child interaction proceed simultaneously. One caregiver attended to parent-theory teaching alone, including: (1) introduction of CMI and encouraging children to participant; (2) appropriate home routines and play routines; (3) learning the way of communication and prompting interaction; (4) prompting communication and developing language; (5) regulating child's emotions; (6) teaching alternatives to challenging behavior; (7) teaching children new skills; (8) self-care and adjustment of caregivers; (9)/(10) practices and comments. At the same time, another caregiver with the child participated group courses divided into music, games, snacks and exercise modules. At the end of the 2-week course, caregivers were encouraged to try their best to apply the theory and intervention skills in the daily life, including home routines and play routines, in order to prompt the ability of cognition, motion, social adaptability and behavior. This study collected the based demographic information, video data and diagnostic sales at two key time-points at least: Baseline(BL); Post-training (PT; within 6 months).

Video-Coded Scheme and Assessment Measures

The collected videos before and after the intervention were coded as the primary outcome variables. The caregivers were encouraged to record 10-minute videos of caregiver-child interaction about home routines or play routines, to evaluate whether

and what the caregivers demonstrated appropriate use of techniques including: (1) environmental sets (i.e., the caregiver sets up the environment and moves to be face to face to promote engagement in play or home routines); (2) offering choices (i.e., the caregivers offers choices for the activity, follows the child's appropriate choices and interests and comments on the child's focus of attention and actions); (3) building and sustaining routines; (4) pauses (i.e., the caregivers pauses and allows space for the child to communicate); (5) responding (i.e., the caregivers notices the child's communication and responds promptly by expanding it by imitation, expansion and modelling of words and gestures); (6) matching (i.e., the caregiver provides communication models that match the child's communication goals, including gestures and spoken language); (7) requesting (i.e., the caregiver sets up the environment to create opportunities for communication to request); (8) sharing (i.e., the caregiver sets up the environment to create opportunities for communication to share); (9) supporting and regulating (i.e., the caregiver supports the child's engagement and regulation throughout the interaction.); (10) different degrees of assistance (i.e., the caregiver promotes child's learning of new skills by using instructional strategies into developmentally appropriate small steps and teaching one step at a time, constructing and applying visual supports as needed, giving lowest level of help needed for the child to be successful, and fading the level of help in a timely way); (11) challenging behaviors (i.e., if challenging behavior occurs, the adult responds by demonstrating use of the appropriate strategies to reduce the behavior and support the child's regulation based on the function of the behavior). Based on those 11 strategies, the question(Q) 1 to 10 of Adult/Child Interaction Fidelity Rating(A/CIFR) is matched with the strategy from (1) to (10) above, and strategy (11) is set as an additional question marked "*". Five degrees every question, they are: 0-The skill/strategy is not demonstrated or inappropriately applied when opportunities are present; 1-The strategy is used somewhat appropriately at times; 2-Implementation of the strategy is mixed- about 50% of the time the strategy is correct; 3-Appropriate and accurate implementation of the strategy occurs up to 80% of the time; 4-Strategies are applied appropriately in 80-100% of opportunities.

In the preliminary stage, the writer watched the reference videos of CMI and learned the corresponding scoring rubrics of A/CIFR scored by experts. Then, the writer and another author trained by experts evaluated 12 videos of 4 children with NDDs (total time: 137'58") synchronously, and the consistency test was 99.24%.

Standardized Measures

Baby-junior high school students ability of social life scale (S-M)(8, 9), based on S-M Social Life Ability Examination established by Japanese Institute of Psychological Adaptation, was revised by professors of Beijing Medical University and Chinese Psychological Society, mainly for Chinese children with mental retardation aged 0-14 years. S-M evaluated six parts of ability, including self-help, locomotion, occupation, communication, socialization and self-direction, as important as Gesell Developmental Scales(GDS) for diagnosis of GDD.

Gesell Developmental Scales(GDS)(10) was compiled by A Gesell, an American psychologist, and revised twice in 1941 and 1980 respectively. It focused on five areas of ability, which were gross motor, fine motor, language, adaptability and individual-social behavior, mainly for children with GDD aged from 4 weeks to 6 years. The result of GDS showed developmental quotient(DQ) instead of intelligence quotient(IQ). It's used widely in China not only as the golden standard for the diagnosis of GDD but also as an auxiliary tool for the diagnosis of ASD. A study(11) showed that the results of GDS indicated developmental backwardness and imbalance in ASD children that the DQ scores in fine motor ability, adaptability, language and individual-social behavior are lower especially in the latter two functions compared with that of gross motor.

Wechsler Preschool and Primary Scale of Intelligence (WPPSI)(12) was one of the three continuous intelligent scales created by Wechsler, a famous American medical psychologist, mainly for children with mental retardation aged 4-6.5 years. WPPSI gave consideration to the ability of both language and operation, which could reflect the intelligence level of preschool and primary children.

Autism Diagnostic Observation Schedule(ADOS) (13)was the golden standard for diagnosis of ASD, identifying ASD symptoms of communication, interaction, game/imagination, stereotyped behaviors and limited interests. According to the

verbal expression level and age, the assessor should choose one of the four modules appropriately.

Analytic Approach

We first compared the results of A/CIFR between BL and PT to evaluate whether caregivers' skills of family intervention improved and whether the longer daily family-intervention period was, the more significant the promotion was. Secondly, by making comparison of assessment scales including S-M, GDS, WPPSI and ADOS between BL and PT, whether children's abilities and symptoms improved through family intervention. What's more, we analyzed whether the caregivers' promotion of intervention skills would be influenced by demographic, including the main caregiver, family structure and household income. We used SPSS 22.0 to manage data. Data also allowed for positive and negative values and were normally distributed (skew ($< |2|$); kurtosis ($< |3.5|$). Nonparametric test (Mann–Whitney U test or Wilcoxon signed-rank test) was used for comparisons between BL and PT for data of scales mentioned above. Spearman Correlation was used to analyze the influence factors on caregivers' skill promotion. $P < 0.05$ was considered statistically significant.

Results

Elementary Analyses

Video quality. To ensure the video quality, we analyzed the whole 120 videos (skew 1.00; kurtosis 4.42), 49 BL and 71 PT videos severally. The median length was 631s and 617s respectively, and there was no difference between two groups ($P = 0.05$) in time.

Standardized measures. All of the 33 children completed S-M before training. 2 of 33 children completed WPPSI instead of GDS because they were over 4 years old and diagnosed as intellectual disability by the initial clinician. According to the verbal expression level and age, different modules were used to evaluate 32 children before training appropriately, and the last one was diagnosed GDD definitely at first, so there was no ADOS assessment. Within 6 months after the training, standardized measures were lack of information because of dissatisfaction of regular follow-up evaluation on specialist clinic. As a whole, the counts of S-M, GDS, WPPSI and ADOS were 33-22, 31-25, 2-0, 32-23 from BL to PT respectively.

Primary Outcomes

Compared with BL, the mean score of Q1, Q3-Q10 and Q marked “*” was higher ($P = 0.01$, $P = 0.05$), with no change from BL to PT ($P = 0.143$) on Q2. Table 2 reported performance on video-coded outcome measures by BL and PT.

Table 2 Comparisons of A/CIFR outcome on video data measures between Baseline and Post-Training

Question	1	2	3	4	5	6	7	8	9	10	*	1-10
Baseline	1.43	0.51	1.67	1.57	1.74	2.10	0.82	1.51	1.47	1.18	1.36	1.40
Mean(SD)	(1.06)	(1.00)	(0.97)	(1.10)	(1.11)	(1.23)	(0.81)	(1.26)	(1.06)	(1.07)	(1.12)	(0.89)
Post-Training	2.68	0.79	2.76	2.55	2.96	3.17	1.61	2.30	2.73	2.58	2.29	2.41
Mean(SD)	(0.98)	(1.17)	(0.90)	(1.13)	(1.01)	(0.97)	(1.22)	(1.49)	(1.00)	(0.84)	(1.14)	(0.82)
R ²	5.69	1.46	5.47	4.31	5.38	4.66	3.55	2.87	5.74	6.35	0.04	5.67
P value ^a	0.01	0.143	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.05	0.01

^a Significance at alpha (0.05/2) by Mann–Whitney U test

According to the principle of self-contrast randomized paired design, we analyzed 75 PT-BL pairs. There was significant change from BL to PT ($P=0.01$). Table 3 presented the contrast. Meanwhile, there was no correlation between the improvement of caregivers' skills and duration of daily family intervention ($\rho=-0.01$, $P=0.05$).

Table 3 Comparisons of A/CIFR outcome on 75-Pair Videos

Variable	count	Mean(SD)	R ²	P value ^a
Post-training-Baseline	75	0.89(0.11)	5.68	≥ 0.01

^a Significance at alpha (0.05/2) by Mann–Whitney U test.

Secondary Outcomes

Table 4 showed standardized measures outcomes between BL and PT. Compared with BL, children's abilities and symptoms improved through family intervention, among which adaptability of GDS and stereotyped behaviors and limited interests of ADOS were significant changes ($P=0.05$, $P=0.01$).

Correlation Analyses

There was mild negative correlation between the rising mean score of Q1-Q10 from BL to PT and parental education($\rho:-0.29$, $P=0.05$), which meant the higher parental education was, the lower improvement of caregivers' intervention skills was, without correlation between the improvement and other demographics, including the main caregiver, family structure and annual household income. Table 5 presented the details.

Table 5 Correlation analysis between improvement and demographics from Baseline to Post-Training

Variable		Father's education	Mother's education	Main caregiver	Family structure	Annual household income
Rising mean score	ρ	-0.29	-0.29	0.01	0.13	-0.19
P value ^a	$P=0.05$	$P=0.05$	0.951	0.270	0.096	

^a Significance at alpha (0.05/2) by Spearman Correlation.

Discussion

Firstly, caregivers can significantly improve their family intervention skills through short-term systematic training. Family-mediated intervention was proved as one of the 27 evidence-based methods by American National Center for Autism Intervention and Professional Development in 2007(6). At the same time, family-mediated intervention was defined as “parents apply personalized intervention strategies learnt from systematic training to improve communication and social skills of children with ASD or reduce their various behavioral problems in the daily life”. At present, it has been lack of systematic and effective family-mediated intervention models reported so far in China(4). One probable reason is that caregivers are diffident to master a series of intervention methods, including behavioral intervention, structured education, social intervention, sensory intervention and comprehensive intervention. In their opinion, it is too professional for them to master those interventions, which should be completed in hospitals, training institutions or schools. The aim of family-mediated intervention models is training caregivers, such a group who are get along with children with NDDs from morning to night, to master and apply intervention strategies in home routines and play routines. The intriguing point is how long it will take to train them at least. On one hand, this study demonstrated that by only ten 90-minute lessons (total training time: 15 hours), 2 weeks a teaching cycle,

a significant promotion of caregivers' intervention skills was observed within 6 months, which means caregivers can significantly improve their family intervention skills through short-term systematic training. On the other hand, this study didn't find correlation between the improvement and the length of intervention time, which meant there was no dose-effect relationship between them. It was possibly thought that the theoretical knowledge of CMI was relatively basic and simple for caregivers, so there was no need to spend long time to practice. From another point of view, that also proves the possibility that caregivers can master intervention skills. During the telephone follow-up with the parents of 33 children, 97% of children participated different intervention models in addition to family intervention within 6 months, including training institutions, special education and integrated education. Therefore, whether exists other influence factors between skill improvement and intervention duration should be studied further.

Secondly, caregiver-mediated intervention may overall contribute improvement of children's abilities and remission of their symptoms. As one of the core symptoms of ASD, social interaction and communication deficit has been the focus of intervention. It was abroad reported that a series of family intervention models mostly aimed to improve skills of communication and social interaction of children with ASD, and actually contributed their sharing positive emotion, initiative communication and social skills in different degrees(14-16). However, as another core symptom of ASD, stereotyped behaviors and limited interests is rarely targeted for intervention. A previous research(17) demonstrated a family intervention effectively improved parents' ability to respond to the symptom instead of reducing it. This study indicated there was a comprehensive improvement on abilities and the severity of the symptoms, among which the change of adaptability and stereotyped behaviors and limited interests were especially significant. Nevertheless, as previously stated, there existed other intervention models synchronously, so the direct correlation between the overall improvement and CMI was difficult to evaluate. Meanwhile, comprehensive intervention was confirmed effective to some extent from another point of view.

Thirdly, caregiver-mediated intervention can be applied in families with different demographics, especially the one which has a lower basic education probably. Currently, it is poorly understood the mechanism of the effect of family intervention model on children with ASD. A systematic review(18) analyzed the role of parent characteristics in parent-mediated interventions(PIM) for children with ASD. That review put forward that parent demographics (i.e. age, nationality, education, family socioeconomic status), mental stress and cognitive characteristics may influence the quality of family intervention including learning of new strategies, goal setting skills and the ability of drawing inferences about other cases from one instance, thus, affecting intervention indirectly. Parent mental stress, as a hot research topic among those characteristics(19), may had complex workings. For one thing, it could be posited that parents with lower level of baseline stress are more likely to attend PIM sessions, show higher engagement and accept training from clinicians. For another, it is possibly that parents with higher levels of baseline stress are more likely to need support and be engaged in PIM sessions. In the meanwhile, parent mental stress can be relieved in the process of coaching by different degrees(20, 21). That review also found maternal age and parent education were nothing to do with the intervention effect. This study presented the lower the parental education was, the more significant the improvement of strategy application was, although it only proved low correlative. The probable reason is that parents with higher education are more likely to access to intervention strategies in daily learning and master some basic method, resulting in smaller room for improvement and less obvious skills improvement, which implies CMI is more suitable for families with a lower basic education probable. In addition, no correlation was found between caregiver outcomes and other demographics. Therefore, to sum up in conclusion, CMI can be applied in families with different demographics widely.

Compared with various family intervention models aboard, there has been shortage in this research field domestically. This study can make up for the deficiency, providing reference for clinical intervention for children with NDDs in a sense. At the same time, based on video-coded data by A/CIFR scale, caregivers' intervention skills are quantified, which contributes to quantitative assessment of caregivers' behaviors and correlation analysis.

Of course, this study has certain limitations. Firstly, the sample was relatively small, which led to gender difference of the samples compared with that of the prevalence of ASD. On the one hand, it was known that 10-minute videos about interaction with children with NDDs were too difficult to record for a part of caregivers, especially for grandparents as the main caregiver. On the other hand, it was generally recommended that children with NDDs be evaluated regularly in the specialist clinic every 3

to 6 months, but in fact, the follow-up rate was unsatisfied. On account of the two sides above, collecting complete data was full of difficulty. Secondly, as the primary outcomes, A/CIFR scale for video-coded data was subjective to some extent, although the author learnt the scale systematically and carried on quality control in the preliminary stage. Thirdly, other interventions weren't forbidden except CMI because of ethical issues, which may have some effect on the evaluation. The follow-up on telephone found that the use of CMI strategies was relatively high frequency, which played an important role in the overall improvement for children. What's more, the focus of CMI was the improvement of caregivers' skills, which was mainly influenced by the intervention of CMI. So in the future clinical work, clinicians should enhance propaganda to let more caregivers realize the importance of follow-up for NDDs, such a disease which emphasize lifelong intervention. Meanwhile, more objective scales should be developed to quantify the intervention effect. What's more, RCTs is better for evaluation.

Conclusions

Training caregivers as mediators of a naturalistic, developmentally sensitive intervention makes allowance for the integration of intervention into families' daily activities, bringing about access to intensive intervention within a child's natural social context. CMI can significantly enhance the family-mediated intervention skills of caregivers in families with NDDs in a short period, and help to overall improve abilities and symptoms of children probably. What's more, as a family-mediated intervention model with little limitation, it can be applied to families with different demographic information. In conclusion, CMI can be considered an effective intervention measure, which deserves to popularized.

Declarations

Ethics approval and consent to participate: The authors assert that all procedures contributing to this work comply with the ethical standards of the Institutional Research Ethics Boards of Children's Hospital of Chongqing Medical University and the ethics boards has approved this study in the subsection Ethics approval and consent to participate. The written informed consent was obtained from all caregivers. What's more, all methods were carried out in accordance with relevant guidelines and regulations. Trial registration: China Clinical Trial Registry (ChiCTR-IOC-17013638, 15/12/2017).

Consent for publication: All participants of our research agree to publish the details of their family information and signed informed consent.

Availability of data and materials: The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests: All authors declare that they have no competing interests.

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Authors' contributions: YD and DG designed the study; DG, YW and HW analyzed the data; XL, YH, LC and QC collected the clinical information; YL and JL performed the Caregiver-Mediated Intervention; YD and DG prepared the manuscript. All authors read and approved the final manuscript.

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Tables 1 And 4

Table 1 Family characteristics of participants

Variable	Classify	Count (NS 33)	Percentage%%
Residence	City	33	100.00
	Country	0	0.00
Main caregiver	Father/mother	11	33.33
	Parents	13	39.39
	Grandparents	9	27.27
Family structure	A couple and their child	10	30.30
	Three generations under one roof	21	63.64
	Four generations under one roof	2	6.06
Father education	Primary or middle school	3	9.09
	High or technical secondary school	5	15.15
	College or junior college	24	72.73
	Master degree and above	1	3.03
Mother education	Primary or middle school	3	9.09
	High or technical secondary school	4	12.12
	College or junior college	25	75.76
	Master degree and above	1	3.03
Annual household income	≤100,000RMB	17	51.52
	110,000-150,000 RMB	7	21.21
	160,000-200,000 RMB	4	12.12
	≥200,000 RMB	5	15.15

Table 4 Standardized measures outcomes between Baseline and Post-Training

GDS ^b					ADOS ^c				
Ability	Gross motor	Fine motor	Language	Individual-social behavior	Communication	Interaction	Communication, interaction (social affection)	Game/imagination	Stereotyped behaviors and limited interests.
5	73.26	71.84	47.13	60.26	4.86	9.13	14.00	2.30	2.09
9)	(14.02)	(17.82)	(14.54)	(11.62)	(2.00)	(2.93)	(4.20)	(1.30)	(1.42)
5	75.88	76.28	52.24	63.80	4.70	7.74	12.48	1.65	1.09
9)	(20.33)	(14.56)	(18.25)	(14.86)	(2.18)	(3.53)	(5.20)	(1.43)	(1.08)
	0.37	1.15	1.01	0.77	-0.17	-1.20	-0.98	-1.85	-2.70
5	0.711	0.248	0.314	0.443	0.863	0.229	0.329	0.064	P=0.01

^a S-M, Baby-junior high school students ability of social life scale; ^b GDS, Gesell Developmental Scales; ^c ADOS, Autism Diagnostic Observation Schedule; ^d Significance at alpha (0.05/2) by Mann-Whitney U test.