Goal-Directed Therapy to Improve Gross Motor Function and the Quality of Life of Children with Cerebral Palsy: A Randomized Controlled Trial

Suwannika Palee, M.D., Teerada Ploypetch, M.D.*, Kingkaew Pajareya, M.D.*, Suttirat Timdang, BSc*.**

**Department of Rehabilitation Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand, **Department of Rehabilitation Medicine, Faculty of Medicine, Naresuan University, Phitsanulok 65000, Thailand.*

ABSTRACT

Background: The multiplicity of interventions for the treatment of cerebral palsy (CP) can cause confusion about which are most suited to certain individuals. Hypothesis is that goal-directed therapy (GDT) can guide integrating therapies to improve clinical outcomes compared with conventional therapy (CT).

Materials and Methods: A prospective, assessor-blinded, randomized controlled trial was done with 23 children with CP (mean age, 4 years 4 months old; SD 1y4mo), who were divided into groups according to their level of gross motor function: GDT and CT. Both groups received 12 physiotherapy (PT) sessions and advice on daily home programs. The GDT group additionally had a team meeting to set a specific goal, and PT programs were shaped toward that goal. Assessments were done at baseline and after treatments, using the Thai-version Gross Motor Function Measure (GMFM-66), CP-Quality of Life (CP-QOL), caregiver burden, and home program compliance.

Results: After the treatments, the GDT group showed significant improvements in GMFM-66, CP-QOL, and caregiver burden, while the CT group revealed improvements in caregiver burden and some domains of the GMFM, including sitting and crawling & kneeling. Comparisons between groups found GDT was more effective than CT in improving GMFM-66 and CP-QOL. Home program compliance was higher in the GDT (69%) than the CT group (42%).

Conclusion: GDT demonstrated clear gains for children with CP regarding gross motor function and QOL improvements. Team communication toward a customized goal was crucial, empowering the children and their caregivers to comply with home programs to achieve the set goal.

Keywords: Cerebral palsy; goal-directed therapy; gross motor function; quality of life; caregiver burden (Siriraj Med J 2022; 74: 1-10)

INTRODUCTION

Cerebral palsy (CP) is one of the most common causes of childhood physical disability[1] and is caused by a non-progressive lesion to the immature brain.[2] This syndrome causes the dysfunctional control of movement and posture, while perception, vision, learning, and language are also frequently affected.[3] These characteristics can influence the child's ability to learn and perform everyday life activities[4], and also the quality of life (QOL) of patients and their caregivers are affected by these disabilities.[5] Treatment program should promote the improvement of the patient's motor function, and facilitate their participation in activities and adaptation to daily living, with the ultimate goal of improving their QOL.[6]

Corresponding author: Teerada Ploypetch
E-mail: teerada.plo@mahidol.ac.th
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ORCID ID: https://orcid.org/0000-0002-5834-6800
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Numerous treatments for CP are available, which can be overwhelming for patients and families, and even make it challenging for healthcare professionals to make a clinical decision on what is the most suitable treatment for each child. Recent systematic reviews provide evidence-based guidance for assessing interventions for children with CP, such as the Evidence Alert Traffic Light system.[7] Here, green-light-go interventions are inferred to be effective with a higher level of evidence, while yellow-light interventions show uncertain effects and require outcome measures to monitor progress, and red-light interventions are considered ineffective and therefore to be avoided.[7] However, this does not suggest that every child with CP should undergo all green-light interventions for best practice since CP has a heterogeneity of symptoms and clinical status. The key to success is doing the right things with the right child at the right time.[8]

Goal-directed therapy (GDT) approach could be a solution to this overwhelming situation. GDT focuses on comprehensive treatment strategies that serve as stepping stones to achieving individual goals, which along the way promote functional performance and a gradual independence in everyday life activities.[9,10,11] The approach consists of the identification of individual needs of both the child and the family, assessments of the child's performance and capacity, setting goals that are meaningful tasks and relevant despite the child's level of gross motor function[12], and the development of individual-tailored treatment programs.[13] Setting specific goals is a means to enhance awareness of the objectives of the therapy and can affect the treatment performance by focusing attention, directing effort, increasing motivation, and enabling the development of strategies to achieve the set goals.[13] There is evidence showing an improvement in basic motor abilities and self-care in young children with CP after undergoing GDT, and a decrease in their need for caregiver assistance for self-care and mobility.[13,14] However, in previous research, the research methodology either did not involve a randomized controlled trial (RCT) and the duration and frequency of treatment in the GDT group setting were three hours per session, five days a week, for a period of three weeks[14] or did and treatment was three days a week for three consecutive months.[13] Additionally, the treatment used in previous studies may be too onerous for patients in many developing countries because of certain socioeconomic problems and human resource issues[15], such as parents finding it inconvenient to bring their children to the hospital because of the cost of travel, lack of time, and limited number of therapists available.[16,17]

Consequently, an RCT was performed to compare GDT and conventional therapy (CT), with reducing the amount of interventions performed at the hospital and encouraging the use of home programs, compatible with the available resources. Currently, conventional therapy is mostly practiced through a physiatrist, who authorizes prescribed treatment programs via the medical records after assessment of a patient and conveyed to the respective rehabilitation team. In contrast, GDT includes a family-team meeting organized to set specific goal(s), with the treatment programs then shaped to meet the set goal. We hypothesized that even with both groups receiving the same amount of hospital programs, GDT would be more effective than CT for improving gross motor function, QOL, caregiver burden, and compliance with home programs.

MATERIALS AND METHODS

Study design

This prospective, assessor-blinded RCT was conducted between April 2018 and April 2019. The study protocol was approved by the Institutional Review Board (COA no. Si 675/2017), and registered with the Thai Clinical Trials Registry (registration no. TCTR20180419002). Forty-five children with CP from a pediatric rehabilitation unit of the university hospital were evaluated for eligibility (Fig 1), with written informed consent obtained from their parents of all participants. The participants were stratified by their severity of CP using Gross Motor Function Classification System (GMFCS)[18], as assessed by a study doctor, and then randomly allocated into either the intervention group (GDT) or control group (CT) by drawing random numbers from a sealed envelope. Computer-generated randomization with block sizes of 4 was used to create the random numbers. The participants were requested to maintain their other treatments, such as oral antispastic medications and orthoses that could be considered co-interventions; however, these could be changed as a medical necessity. The researcher regularly monitored and recorded whether additional therapies were used by the participants.

Participants

Eligible participants were children with CP, GMFCS levels I–IV, aged 1–6 years old, able to understand basic instructions and communicate pain or discomfort, and having caregivers with Thai language literacy who were able to complete the questionnaires. The exclusion criteria were specifically patients with uncontrolled epilepsy, history of fractures, serial casting, orthopedic surgery or chemoneurolysis intervention within 6 months

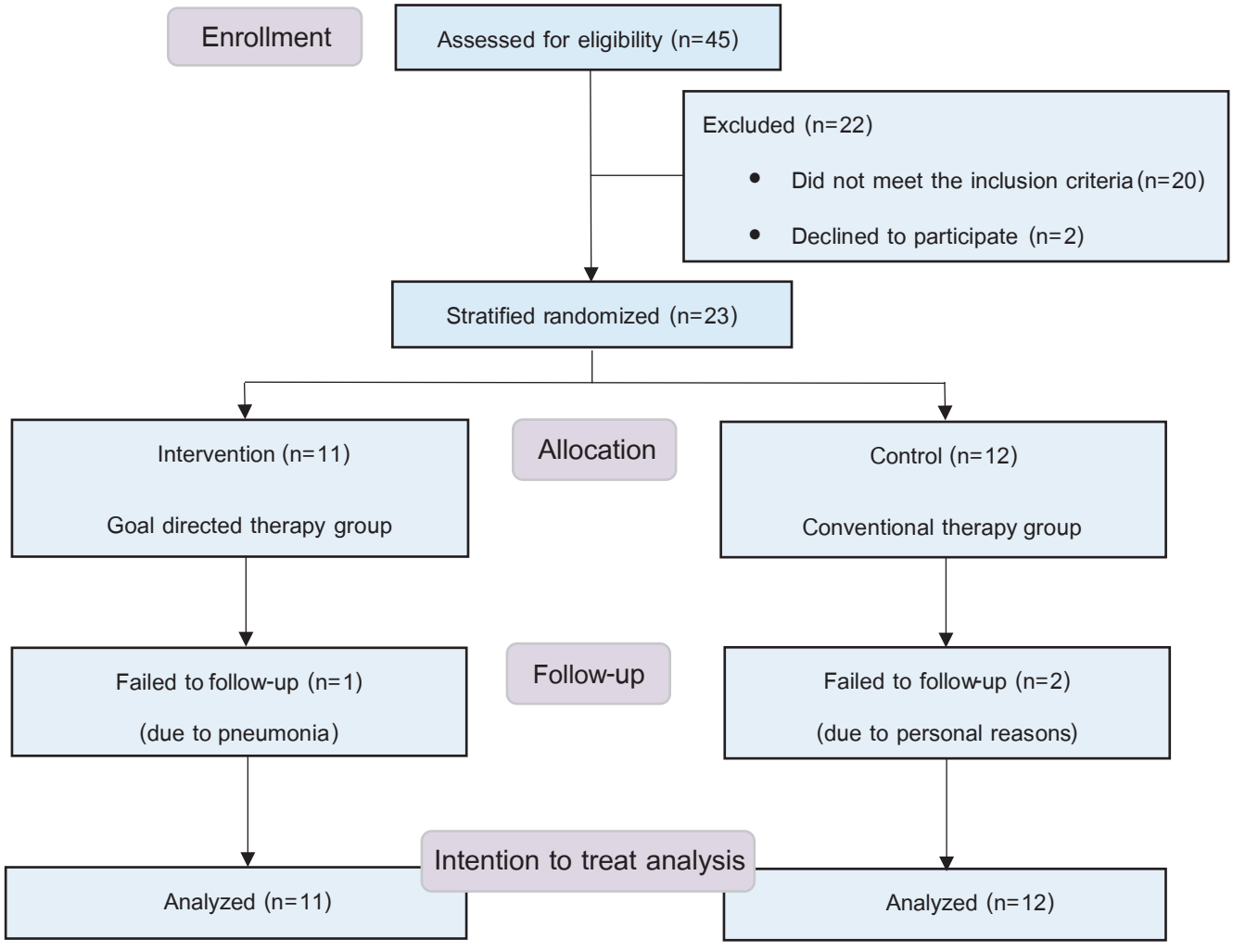

Fig 1. Consolidated Standards of Reporting Trails (CONSORT) diagram showing the flow of participants in the study

prior to the study, known unstable cardiovascular or pulmonary diseases, and any contraindication for receiving physiotherapy (PT), or declined to participate.

The sample size calculation was based on a previous study.[13] The nQuery, with a type-I error at 0.05 and 80% power of test, indicated that at least 10 participants per group would be required to detect a statistically significant difference in gross motor function improvement between the two groups. The recruitment process was on a first-come-first-served basis until the target number of 23 children had been reached, to compensate for potential loss to follow-up about 10%.

Interventions

Attending physiatrists evaluated all participants and prescribed individualized PT programs, such as hydrotherapy, bicycling, strengthening and stretching exercises, balance and mobility training, modalities, and tools applications. Both groups received 50 minutes of PT for 12 sessions. The therapists assigned daily home exercise programs suitable for each patient. Caregivers were responsible for the home programs and for recording their compliance in a logbook (Fig 2).

For GDT group, an additional process was included, which was a team conference involving the physiatrist, physical therapist, child, and caregivers, where an individualized goal was agreed for each patient. The goal-development process included an assessment of the child's performance and motor capacity, identification of a specific, measurable, achievable, relevant, and timed (SMART) goal, and the conception of the goal-attainment scale (GAS).[14,19] Only one goal was set as the most crucial and relevant to the child and family's needs, and that was possible to achieve based on each child's assessed performance. PT programs were adjusted specifically for goal achievement. The GAS was used to objectively identify and follow progress. For example, if the goal was to sit independently for 30 seconds, the programs emphasized

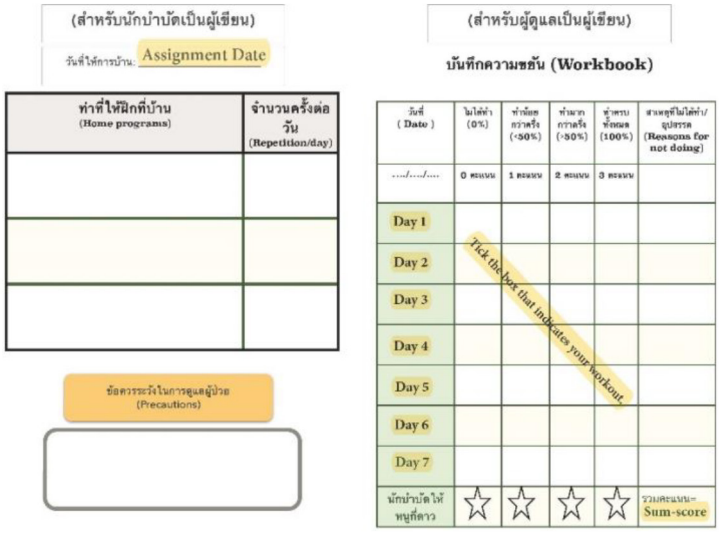

Fig 2. A logbook for recording home program compliance.

exercises to promote core/trunk muscle strengthening and sitting balance. Others programs, such as stretching heel cords or mobilization, were still considered crucial, but were not intensively assigned because these were not related to the set goal. The individualized specific goal was presented in the cover of the logbook for the GDT group to remind all the team and family members of that goal.

Outcome measurements

A study doctor retrieved demographic data, GMFCS level, type of CP, and co-morbidities. The primary outcome of this study was the improvement of gross motor function after the therapy. A blinded physical therapist, who had experience but was not involved in any of the therapy sessions, assessed the participants using the Gross Motor Function Measure (GMFM-66) Thai version[20], a standardized tool for measuring gross motor function in children with CP that contains 66 items for assessing gross motor ability, including: (1) lying and rolling, (2) sitting, (3) crawling and kneeling, (4) standing, and (5) walking. The final GMFM-66 score was calculated with a computer-scoring program: the Gross Motor Ability Estimator. The maximum score is 100, and a higher score means better gross motor function. Here, a change in GMFM-66 score of 1.58 was reported as a clinically meaningful improvement, and a score change of 3.71 could discriminate between great and not great improvement.[21]

Secondary outcomes were the children's QOL, caregiver burden, and home program compliance, assessed by the CP-QOL Questionnaire Parent Proxy Thai version[22], the CP Caregiver Burden Thai version[23], and logbook scoring (Fig 2), respectively. Those questionnaires and a survey for the caregivers' demographic data were self-administered by the caregivers, with the primary caregiver, as the main person the child spends most time with, the preferred candidate to answer the questionnaires, or the other caregivers if the primary caregiver was not available. Outcome measurements were recorded at baseline and immediately after the 12th session of therapy.

In the GDT group, goal achievement was evaluated after completion of all the therapy sessions using the GAS, a tool for identifying specific goals and measuring progress. This assessment was done by the physical therapist who provided the GDT. The GAS consists of 6 grades: -3, for worse than at the start (i.e., a deterioration); -2, for equal to at the start; -1, for less than expected; 0, for expected goal; +1, for somewhat more than expected; and +2, for much more than expected.[24]

Statistical analysis

The analyses were performed using SPSS Statistics version 18.0 (SPSS, Inc., Chicago, IL, USA). A p-value <0.05 was regarded as statistically significant. Data are presented as the number and percentage for categorical variables, and the mean ± standard deviation (SD) for continuous variables. The baseline patients' characteristics and the results of both groups were assessed for normality using the Kolmogorov–Smirnov test. Chi-square or Fisher's exact test were used to compare categorical variables. For continuous variables, the Student's t-test was used to compare parametric data, and the Mann–Whitney U test was used to compare nonparametric data. Statistical analysis was finally performed by intention to treat analysis. Missing data were replaced by the last observation value.

RESULTS

The study participants comprised 23 children with CP (mean age, 4 years 4 months old; SD 1y4mo). The mean time interval between baseline and final assessments for all was 93.1 (SD 36.3) days. The participants' baseline characteristics are presented in Table 1. Participants in both groups received co-interventions, such as oral antispastic medications and orthotic use, with no statistically significant difference between the groups.

All participants in the GDT group had a team meeting to set a SMART goal related to gross motor function. All showed an improvement from baseline according to their individualized GAS, except one child that was lost to follow-up due to pneumonia. Overall, 6 from 11 children achieved their goals as expected or more than expected (GAS>0).

Comparison of the outcomes before and after the therapies is demonstrated in Table 2. The GDT group showed substantial improvements in GMFM-66 total score and all aspects of gross motor function except for walking & running. The CT group showed no significant improvement in GMFM-66 total score, but improvements in sitting and crawling & kneeling. CP-QOL was significantly increased only in the GDT group, while caregiver burden was decreased after the treatments in both groups.

Comparison of the improvements between the groups is shown in Table 3. The GDT group had significantly higher improvement in GMFM-66 total score and in walking & running subscale compared with the CT group. The increments of CP-QOL in the GDT group were significantly higher than in the CT group, while the decrements of caregiver burden were not different between groups.

Home program compliance was higher in GDT (69%) than CT (42%) group (p=0.010). All participants in the GDT group complied with performing more than half of the assigned tasks; while in the CT group, only 16% complied. Examples of logbook are shown. A participant in GDT group aimed to walk with a walker and well complied with walking exercise at home (Fig 3), while one in CT group revealed moderate compliance (Fig 4).

DISCUSSION

GDT showed superior outcomes compared with CT in improving gross motor function and the QOL of children with CP, consistent with previous studies[13,14,19], even if the dose of treatment at the hospital in this study was limited to just once or twice a week for 12 sessions. GDT facilitated good compliance with home exercise programs, whereby the children still received a high intensity of therapies from their caregivers. Healthcare professionals acted as a coach and trained the caregivers as therapists, which could be practically applied in patients with socioeconomic issues limiting them visiting hospital frequently.[16] This model may also applied in low- to middle-income countries with limited human resources.

GDT resulted in a higher improvement in gross motor function, when compared with CT. Although the amount of therapies performed in the hospital was similar in both groups, the GDT group managed to achieve a greater dosage of therapeutic exercise at home. It is known that strength and muscle endurance affect gross motor outcomes and depend on the amount of intervention the patient receives, so consistently performing exercises can increase strength and endurance.[25,26] In addition, the PT program can be set to integrate specific activities to promote goal achievement. Therefore, those could be reasons for the greater improvement of gross motor outcomes in this group. Gross motor function improvement after GDT was clinically meaningful: the average change of GMFM-66 of 11.7±6.8 showed great improvement[21], most likely due to the very young age of the participants in this study, which is well-known to offer a higher chance of gross motor improvement.[21]

It is known that the standard practice of rehabilitation is goal oriented. Treatment programs in CT should be also for serving goals, considering that physiatrists prescribed those for individuals. The lower outcomes might be from ineffective communication about the goals. As a result, team members could not realize what programs to focus on and a lack of motivation to comply. The predominant home program compliance in GDT group was possibly due to the team meeting including a number of key elements for enhancing adherence to the prescribed home programs, especially effective goal setting. Here, a SMART goal was set by consensus between the multidisciplinary team and the patients' caregivers, which helped tailoring the goals to the patients' needs. One goal was chosen for each patient that was possible for them to achieve easily to encourage and motivate their adherence to physiotherapy rather than setting more difficult or multiple goals.[27] The use of GAS encouraged communication and collaboration between the team members, and facilitated patient and family involvement.[28] Moreover, the team meeting expedited effective communication, which enhanced reciprocal relationships, ameliorated problems, and facilitated caregiver/parental empowerment by their engagement with the professionals, who were perceived as collaborators instead of authoritative experts. Empowerment, motivation,

TABLE 1. Baseline characteristics of the participants and their caregivers.

	GDT group (n=11)	CT group (n=12)	*p-value*
Participants' data			
Female gender, n (%)	6 (54.5%)	6 (50.0%)	0.837
Age (years)[1]	4.4 ± 1.2	3.6 ± 1.4	0.183
GMFCS level[2], n (%)			0.925
I–II	7 (63.6%)	7 (58.3%)	
III–IV	4 (36.4%)	5 (41.7%)	
Topography classification, n (%)			0.169
Unilateral type	7 (63.6%)	4 (33.3%)	
Bilateral type	4 (36.4%)	8 (66.7%)	
Comorbid disease, n (%)			
Intellectual disability	8 (72.7%)	7 (58.3%)	0.492
Epilepsy	2 (18.1%)	2 (16.6%)	0.928
Duration of treatments (days)[1]	105.0 ± 40.9	82.1 ± 29.0	0.199
GMFM-66 at baseline[1]	68.6 ± 17.1	55.6 ± 21.5	0.140
Caregivers' data			
Age (years)[1]	47.3 ± 12.9	43.2 ± 16.0	0.570
Relation to participants, n (%)			0.314
Primary caregiver	4 (36.4%)	7 (58.3%)	
Other caregiver	7 (63.6%)	5 (41.7%)	
Family income, n (%)			0.543
Not enough to use	6 (54.5%)	4 (33.3%)	
Enough to use	3 (27.3%)	6 (50.0%)	
Retained	2 (18.2%)	2 (16.7%)	
Education level, n (%)			0.708
Undergraduate	9 (81.8%)	9 (75.0%)	
≥ Bachelor's degree	2 (18.2%)	3 (25.0%)	

[1]Mean ± SD, [2]GMFCS = Gross Motor Function Classification System.

TABLE 2. Outcomes comparison within the goal-directed therapy (GDT) and conventional therapy (CT) groups.

Outcomes	GDT (n=11)			CT (n=12)		
	Before	After	*p-value*	Before	After	*p-value*
GMFM-66[1]						
Total score	68.6 ± 17.1	80.3 ± 11.8	0.013*	55.6 ± 21.5	60.3 ± 21.7	0.132
Lying & rolling	90.2 ± 14.3	99.4 ± 1.3	0.006*	80.5 ± 16.3	84.33 ± 15.3	0.157
Sitting	87.0 ± 16.2	96.4 ± 6.7	0.006*	69.2 ± 21.6	75.0 ± 21.3	0.039*
Crawling & kneeling	75.6 ± 12.0	87.4 ± 10.6	0.027*	60.4 ± 16.8	70.6 ± 20.9	0.024*
Standing	54.3 ± 31.2	70.4 ± 27.3	0.021*	38.0 ± 25.4	41.4 ± 26.5	0.202
Walking & running	35.3 ± 22.1	48.3 ± 20.4	0.115	30.42 ± 31.9	30.5 ± 29.9	0.678
CPQOL[1]	313.9 ± 59.3	349.3 ± 52.5	0.046*	301.8± 29.9	310.5± 31.8	0.543
Caregiver burden[1]						
Time usage	43.6 ± 18.5	34.6 ± 15.6	0.037*	50.9 ± 11.0	42.1 ± 12.4	0.041*
Difficulty	42.9 ± 17.0	31.9 ± 13.3	0.043*	46.5 ± 7.2	35.6 ± 9.1	0.047*

[1] Mean ± SD, **p-value* ≤ 0.05.

TABLE 3. Comparison of the improvements after the completion of goal-directed therapy (GDT) and conventional therapy (CT).

Outcomes	Score difference (post – pre-treatment)		*p-value*	Difference (95% CI)
	GDT	CT		
GMFM-66[1]				
Total score	11.7 ± 6.8	4.5 ± 3.9	0.011*	7.2 (2.3-12.0)
Lying & rolling	9.2 ± 13.2	3.7 ± 4.7	0.243	5.5 (-2.9-13.9)
Sitting	9.4 ± 11.2	5.8 ± 7.1	0.399	3.6 (-4.5-11.8)
Crawling & kneeling	11.8 ± 4.4	10.2 ± 12.7	0.683	1.6 (-7.2-10.4)
Standing	16.1 ± 19.2	3.4 ± 8.6	0.078	12.7 (-0.1-25.5)
Walking & running	13 ± 7.4	0.1 ± 3.7	0.000*	12.9 (7.8-18.0)
CPQOL[1]	32.1 ± 25.9	8.6 ± 3.6	0.013*	23.4 (5.9-41.0)
Caregiver burden[1]				
Time usage	-9.0 ± 3.6	-8.7 ± 3.8	0.875	0.25 (-3.5-3.0)
Difficulty	-11.0 ± 4.8	-11.7 ± 3.8	0.684	-0.75 (-3.0-4.5)

[1] Mean ± SD, **p-value* ≤ 0.05.

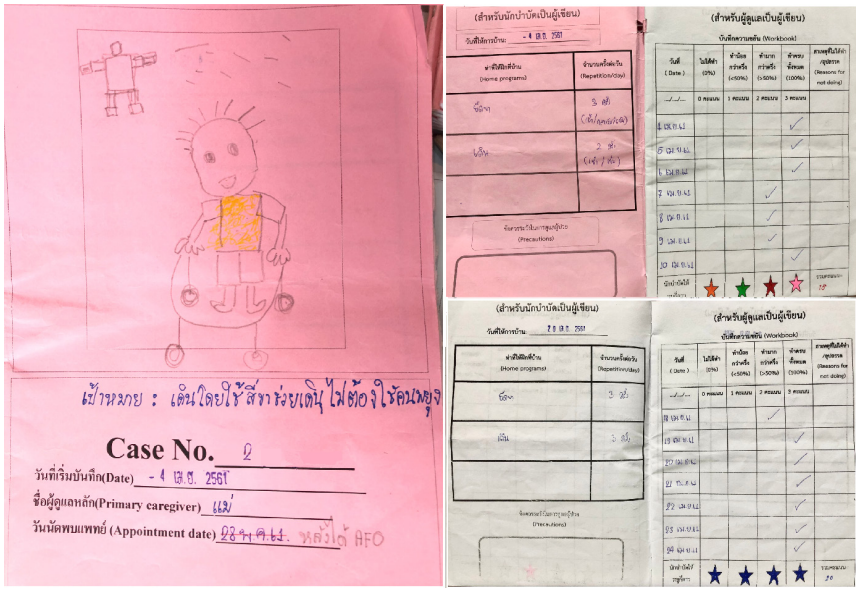

Fig 3. An example of logbook of a participant in the goal-directed therapy (GDT) group

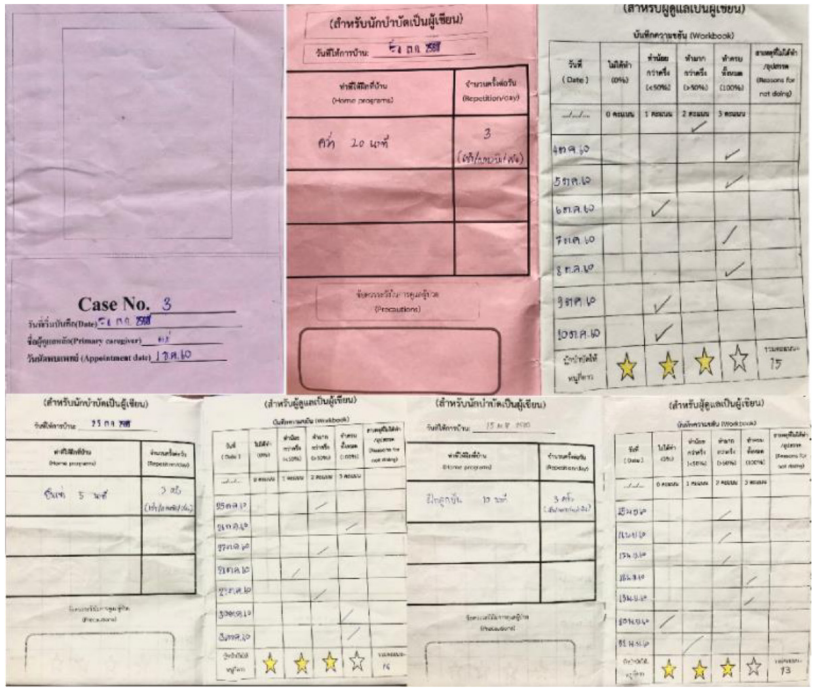

Fig 4. An example of logbook of a participant in the conventional therapy (CT) group

and reciprocal relationships are known determinants of effective parent-delivered therapy in children with CP.[29]

Caregivers' perception of their children's QOL increased after GDT. Previous studies reported gross motor function, cognitive level, complications, pain, and parental stress as factors associated with the QOL of children with CP.[5,30,31] Therefore, the improved QOL in the present study was possibly related to the improvement of gross motor function after treatment. GDT was more effective toward improving gross motor function; consequently, the QOL increment in the GDT group was higher than in the CT. Additionally, effective communication between the multidisciplinary professionals and caregivers via the team meeting in GDT possibly reduced caregivers' stress level, which might have influenced how they reported their child's QOL.[32,33]

Interestingly, caregiver burden was improved in both groups. Considering that the caregivers had to bring their child to the hospital for the PT programs and they were also instructed to spend time doing home exercise programs, in addition to their routine time spent helping the child with daily activities, like eating, personal care, etc., this seemed to be their socio-structural constraints or the objective burdens.[34] Another aspect of caregiver

burden is the subjective burden or emotional distress, which may diminish over time by being able to identify positive aspects of their special parenthood.[34] Family empowerment through home program education was applied to all the caregivers in this study. The results support the findings of a previous study in Thailand, whereby interventions that empowered caregivers' ability to care for their child could reduce caregiver burden.[23]

There are limitations in this study. The physical therapists could not blinded due to the nature of the intervention. Consequently, the therapists who believed in GDT might have put in more effort during the therapy sessions. However, this might be another key to the success of GDT, in that the therapists, as key team members, would do their best for each child to achieve their set goal. Such a potential bias could be reduced by using a blinded assessor and an objective primary assessment tool. Considering baseline parameters, topography, duration of treatment and initial GMFM seemed to favor GDT although those were not statistically significant difference between groups. The nature of children continues to develop over time. Pattern of paralysis and gross motor function at baseline were predictors for good outcome after some interventions.[35,36] Children with a lower initial GMFM achieved higher improvement after selective dorsal rhizotomy.[36] Consequently, assessing a longer period of follow-up and the factors associated with the success of GDT could be very interesting for future studies.

CONCLUSION

GDT demonstrated clear gains for children with CP for improving their gross motor function and QOL. The keys to success are: 1) customized SMART goal setting, 2) focus on integrative therapies to serve meeting that goal, 3) effective communication among multidisciplinary professionals, caregivers, and the child, and 4) family empowerment. In limited resource settings where hospital PT programs could be utilized just once or twice a week, GDT still showed impressive outcomes. Home programs could be a solution to maximize the intensity of interventions. Patients and caregivers are an important part of success, especially once they are motivated and voluntarily make a commitment to comply with home programs to achieve their goals.

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