

Effects of Caregivers-Centered Package on Functional Balance and Activities of Daily Living in Children with Cerebral Palsy: Randomized Control Trial

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Background: Children with cerebral palsy require interdisciplinary treatment due to their multifunctional deficits. Consequently, high levels of stress, worry, and dread of the unknown are common among caregivers. Therefore, understanding cerebral palsy is crucial for caregiver adjustment and role preparation. But there is a dearth of scientific data on the most effective way to teach caregivers. The **aim of this trial** was to evaluate the effects of caregivers-centered package on functional balance and activities of daily living in children with cerebral palsy. **Design:** A randomized controlled trial was implemented in out-patient clinic affiliated with Mansoura University Children's Hospital. A total sample size of 80 caregivers and their children was recruited using a randomization technique. Data collection tools were four: a structured interview questionnaire sheet for caregivers' knowledge regarding CP; caregivers' care reporting sheet; cerebral palsy quality of life scale for children; and pediatric balance scale. **Results:** It was evident that the study group who received educational package demonstrated highly statistical improvements regarding cerebral palsy knowledge and practice ($P \leq 0.001$), compared to the control group results, which showed insignificant differences ($P = 0.246$ and $P = 0.06$, respectively) at the three study phases. **Conclusion:** The educational package for caregivers had an improving effect on their knowledge and practice regarding cerebral palsy, in addition to its positive effect on their children's quality of life and functional balance. **Recommendation:** Developing and implementing an educational initiative for mothers regarding care of their children with CP continuously.

Keywords: Caregivers, Package, Cerebral Palsy, Children, Quality of Life, Functional Balance.

Introduction:

Children with cerebral palsy (CP) have non-progressive, incurable brain damage that prevents their brains from fully developing, which affects their posture and mobility. It is occurring at nearly 2.1 per 1000 live births in low-income countries with larger populations (Mushta et al., 2022). It ranges from 1.4 to 1.7 per 1000 live births, but is lower in high-income

nations where the prevalence is decreasing (Larsen et al., 2021). Cerebral palsy represents 67% of the severe motor disabilities in childhood. Although some risk factors have been identified, including placental abnormalities, birth asphyxia, and neonatal medical problems, the etiology of CP is not well understood (Baraka, El-Sayed, ELShahawy, & Farag, 2019).

Cerebral palsy affects children in a variety of ways, including chronic pain, sensory impairments, vision, and language issues, as well as learning disabilities, social, behavioral, communicative, and nutritional problems. They also face numerous obstacles in performing self-care duties, including eating, dressing, moving, and bathing, which can result in long-term care requirements significantly greater than those of typical children (Gad, Khalil, & AbouZeid, 2023; Baiee, Al Doori & Hassan, 2019). Therefore, to attain the child's independence and community participation, managing children with CP necessitates a coordinated and multidisciplinary approach (Fejes, Beatrix, & Katalin, 2019).

Evidence shows that the parents of children with disabilities in low-resource countries are more likely to experience stress, a higher rate of anxiety and depression, emotional and cognitive problems, and a greater likelihood of having a physical illness (Zuurmond et al., 2018). The scarcity of rehabilitation services in low and middle-income countries (LMICs) can result in families providing the majority of care for their CP child, often with little or no access to training and support (Gutenbrunner & Nugraha, 2018).

Specifically in Egypt, medical rehabilitation services have been described as being minimal (Gutenbrunner & Nugraha, 2018). While there have been calls for more community and home-based interventions as educational and training programs to improve care and support, emphasizing the central role of families (Zuurmond et al., 2018), these are currently

lacking, and there is a dearth of studies evaluating their impact on children and their caregivers. In response to this recognized need, this study aimed at determining the differential effects of an educational package both on the knowledge and practice of caregivers of CP children, as well as on their children's outcomes.

Significance of the study:

Cerebral palsy (CP) is a complex disorder that is typified by common movement impairments and balance issues. It can impede a child's development by impairing their capacity to learn, communicate, and become self-sufficient (Davis et al., 2019). It is regarded as one of the main factors contributing to caregivers' psychological stress and sadness. More than 3.4 million children in Egypt are disabled, 76.117 of them have cerebral palsy (El-Tallawy & Farghaly, 2018). More educational and training resources are required to help caregivers especially mothers of children with cerebral palsy deal with day-to-day challenges (Taylor, 2018). Consequently, a package of education can enhance the caregiver's understanding and application of care of children with cerebral palsy. Additionally, enhance children's functional abilities, balance, and capacity to carry out daily task.

Aim of the study:

To evaluate the effect of caregivers-centered package on functional balance and activities of daily living in children with cerebral palsy.

Subjects and methods:**Research design:**

This study was implemented through a prospective, randomized, controlled trial.

Research Hypotheses:

To achieve the study's aim, the following research hypotheses were developed:

-The post-mean caregivers' knowledge and practices towards cerebral palsy in the study group would be better than the control group.

- Children in the study group whose caregiver received educational package are expected to have good functional balance daily living activities and good quality of life.

Settings:

This study was conducted at out-patient clinic affiliated with Mansoura University Children's Hospital.

Subjects:

The study selected a purposive sample of 40 caregivers with their CP children that was randomly divided into two groups (each group contains 40 caregivers with their CP children) using a simple random technique by using a coin (king and writing) for each caregiver of CP children admitted to the outpatient clinic during the period of data collection within six months. The study group was the king (received the educational package), and the control group was the writing, which received standard of care.

Inclusion criteria for children

children were enrolled if they had a confirmed diagnosis of cerebral palsy (of any type); both genders; aged 4–12 years

Exclusion criteria for children

Children were expelled from the study if they were not suffering from any comorbid neurological disorders; not undergoing any type of surgeries or fractures; spasticity grade 1 according to the Modified Ashworth Scale; Gross Motor Function Classification System (levels I and II);

Inclusion criteria for caregivers

the caregivers who did not receive any educational or training program about CP and accepted to participate in the study.

Sample size calculation:

Sample size was determined by using the power analysis program of ClinCalc Statistical Software, and based on the study parameters of Kim, & Kim (2019), the effect size was large (0.8), target population is 360 people in the last year, the study power was 95%, Expected frequency is 50% and the α error was set at 10%. For the minimum acceptable sample size of 34 for each group, an additional 15% was added to allow for participants dropping out of the study, resulting in a final sample size of Eighty children with their parents that were chosen for the study sample, and they were divided into studied and controlled groups utilizing the randomized block procedure to be 40 for each group.

Data collection methods:

Data collection was implemented by using the following tools.

Tool I: A structured interview questionnaire sheet for Caregivers regarding CP' knowledge

This tool was designed based on the related literature and the researcher created it in a

simple Arabic language. (Hashem & Abd El Aziz, 2018; Baraka et al., 2019; Ajayi, Fatudimu, & Hamzat, 2022; Ahmed, Khalil, & AbouZeid, 2023). It involved two parts. **Part (1)** was about socio-demographic data of caregivers such as age, educational level, occupation, marital status, relationship with child, number of siblings, residence, and previous attendance of training about management of cerebral palsy.

Part (2): It included open questions related to caregivers' knowledge about cerebral palsy's definition, causes, risk factors, clinical manifestations, investigations, alarming signs of seizures, problems associated with the disease, and how to deal with and care for their children. Each correct answer was scored (1), while an incorrect answer was scored (0). The total knowledge score was classified based on Sayed, Abdelmonem, and Ahmed (2021) study as follows: good knowledge was $\geq 75\%$; average knowledge was $50\% - < 75\%$; and poor knowledge was $< 50\%$ of the total score.

Tool II: Caregivers' Care Reporting Sheet:

It was constructed by the researchers after reviewing the related literature (Zuurmond et al., 2018; Ahmed et al., 2023; Kim & Kim, 2019; Baraka et al., 2019; Ansa, Mprah, Moses, Owusu, & Acheampong, 2021) to assess caregivers' care provided to their children (hygienic care, seizures' care, playing and sports activities, care of motor disorders, and communication with others). The steps of the reported practice were evaluated using done or not done practice; (1) mark was awarded for done, and (0) was awarded for not done. The total practice score was categorized on Ahmed et al. (2023) study as follows: adequate practice was $\geq 60\%$,

and inadequate practice was $< 60\%$ of the total score.

Tool III: Cerebral Palsy Quality of Life Scale for Children

It covered two sections:

Part (1) concerned with a clinical profile of the CP children, including age, gender, ranking, education level, family history, and associated health problems of cerebral palsy.

Part (2) concerned about (The Peds QL4.0 generic core scale) **that created by Varni (2014)** to measure the health-related quality of life for children with cerebral palsy. Eight items are for physical functioning, five items are for emotional functioning, five items are for social functioning, and five items are for school functioning. There are four possible scores for each item. Subsequently, the elements undergo reverse scoring and linear transformation, taking values of $0 = 100$, $1 = 75$, $2 = 50$, $3 = 25$, and $4 = 0$. Sayed et al. (2021) classified the overall quality of life score into three categories: low QOL, which is less than 60% of the whole score; moderate QOL, which is between 60% and 75% of the total score; and high QOL, which is greater than 75% of the entire score.

Tool IV: Pediatric Balance Scale was developed by Franjoine et al. (2003). The purpose of PBS is to examine functional balance in the context of daily life's activities in the pediatric population. It involves 14 items. Scoring for each item is 0 points (lowest function) to 4 points (highest function) depending on the quality of performance, with a maximum score of 56 points. The total score ranged from 0 to 56 points, as a higher score indicating better

functional balance which categorized as the following:

-low functional balance is indicated by total scores from 0 to 34

-Moderate functional balance is indicated by total scores from 35 to 42

-high functional balance is indicated by total scores from 43 to 56

Methods:

An official approval to conduct the study was obtained by the researchers through letters directed from the Faculty of Nursing to the director of Mansoura University Children's Hospital to conduct this study, explaining the study's aim and procedures together with its potential benefits.

Field work:

Data collection started, and continued for a period of 6months from the beginning of August to January in 2023

Preparation and development of the educational package about cerebral palsy.

Firstly, the process of the cerebral palsy package's development was based on the updated evidence and on the findings of the need assessment of the caregivers by collecting preliminary data about their knowledge and reported practice level towards cerebral palsy (CP) by using **Tools I &II**, in addition to assessing baseline data of their CP children's balance and quality of life. **Secondly**, the formulation of the first CP package draft included 1); the planning of an educational program' sessions to introduce the contents of the educational program as well as the preparation of the

assisted materials (booklet, pamphlets, and videos). Then, the content validity index of the CP package was evaluated by academic experts, and field professionals for the effectiveness of the CP package and emerged as **(0.91)** regarding its content, language, layout, and illustrations.

Ten percent of the sample size of both the studied subjects, (4 in each group of caregivers (study & control) and 4 in each group of children (study & control)), who were omitted from the study, participated in **a pilot study** to test the face validity of the initial draft of the CP package's aided materials and tools. The requisite adjustments made by the specialists and caretakers in the pilot program were thus put into effect. Additionally, the reliability of caregivers' care reporting sheet, cerebral palsy quality of life scale for children, and the pediatric balance scale was tested by Cronbach's α which emerged as good reliability (0.80, 0.74, and .94 respectively).

During the implementation phase, the educational program time table was distributed among the participating caregivers individually before the start of the program. On the first day of the program, the researchers gave an introductory PPT on the overview of educational program components, which lasted 10 minutes.

The educational package program was implemented through three sessions included 1); one theoretical session about CP' causes, risk factors, clinical manifestations, investigations, alarming signs of seizures, problems associated with the disease, how to deal with and care for

their children as well as the importance/benefits of implementing their practical knowledge regarding CP for both caregivers and children. 2); two practical sessions regarding caregivers' performance for children's' hygienic care, seizures' care, playing and sports activities, care of motor disorders, and communication with others.

Different teaching methods were used in this program as lectures, group discussion, demonstration, and role-playing. In addition, various assisted educational materials, such as guiding booklet, pamphlets, and validated videos, were hired by the researchers.

During the evaluation phase, the CP package was reassessed two times (immediately after and three months for post test follow-up) after the package's implementation.

Immediately after the program, the caregivers' knowledge and reported practice towards cerebral palsy were reassessed by **Tool I** and **Tool II**. After three months of the package's implementation, the CP children's outcomes (balance and quality of life) were reassessed using **Tools III& IV**, in addition to the caregivers' knowledge and reported practice towards cerebral palsy.

Ethical considerations:

Ethical approval No (0521) was obtained from the research ethics committee of the faculty of Nursing, Mansoura University. Verbal informed consent was also obtained from the caregivers who participated in the study for answering the questionnaires after being informed about their right to withdraw from the study at any time.

Statistical analysis:

Data was analyzed using Statistical Package for Social Sciences (SPSS) version 20 (SPSS Inc., Chicago, IL, USA). The descriptive data was presented using mean and standard deviation (SD) for continuous variables and percentage for qualitative variables. For the inferential analysis, RM-ANOVA, Chi-square, and t tests were used to test the research hypotheses. The significance level was set at 5%.

Results:

Socio-demographic and clinical characteristics of the caregivers and their children:

Table (1) shows insignificant difference between the two groups of caregivers in all the previously mentioned characteristics at (**P>0.05**). The mean ages of the caregivers in the study' and control' groups were 39.42 ± 6.74 , and 40.90 ± 7.12 , respectively. More than half of the caregivers in the study' group (52.5%) had diplomas, and two-thirds of them in the control group (67.5%) had bachelor's degrees. In both groups, the occupations of participants weren't working or housewives (study' group: 42.5%, control group: 55%). As regards marital status, nearly two-thirds of both groups (62.5%) were married. Concerning residence, 60% of the study and 47.5% of the control groups resided in urban areas. Regarding the number of siblings, less than half of both groups had one sibling. In terms of previous attendance at education about the management of cerebral palsy, a large percent of both groups didn't attend any educational

courses (study' group: 70%, and controlled group: 80%).

Regarding CP children's characteristics in **table (2)**, the mean age of CP children was 9.25 ± 2.59 and 8.75 ± 2.46 in the study and control' groups, respectively. Fifty two point five percent of children in the study and 35% of them in the control groups were females who studied at the primary level; besides, they were the second children. Nearly 40% of them in the study and 42.5% of the control groups suffer from behavior abnormalities. Regarding children's family history, it was indicated that 57.5% of them in the study and 70% of them in the control groups had a family history of cerebral palsy.

Percentage distributions of Caregivers knowledge about CP

Table (3) illustrates the distribution of caregivers' knowledge in both groups regarding the cerebral palsy' definition, risk factors, clinical presentation, and diagnosis throughout the three study' phases. At the pre-test assessment, average knowledge scores were reported by both caregivers' groups regarding the definition and investigation categories, while "good" knowledge score was reported towards clinical presentation. Compared to the immediate post-test, these knowledge scores elevated in the study' group but remained lower in the controlled group as follows: definition and etiology (study' group: 1.77 ± 0.42 , and control' group: 1.15 ± 0.62); risk factors (study' group: 12.35 ± 2.71 , and control' group: 3.35 ± 3.17); clinical presentation (study' group: 7.80 ± 0.60 , and control' group: 7.80 ± 0.60); and investigations (study' group: 4.85 ± 2.87 ,

and control' group: 2.70 ± 0.46). Similarly, three-months follow-up results reported the same higher results in the studied group's mean scores of all previously mentioned knowledge categories, in contrast to the same lower knowledge results in the control group. Additionally, the RM-ANOVA results of the study' group indicated high statistical differences with a huge effect size regarding all previous knowledge categories ($p \leq 0.001$), compared with the insignificant differences reported in the control group at the three study times ($P = 0.09$, $P = 0.073$, $P = 0.056$, and $P = 0.055$, respectively).

Table (4) portrays the distribution of caregivers' knowledge in both groups regarding cerebral palsy' management and signs of seizure. At the baseline survey, lower knowledge' mean scores were indicated by both the studied groups regarding both knowledge categories. Compared to immediate post-tests, the study group showed higher mean scores, in contrast to the control group, who reported lower knowledge mean scores: cerebral palsy management (study' group: 7.72 ± 0.64 , and control' group: 5.07 ± 1.81); and signs of seizures attack (study' group: 10.0 ± 0.0 , and control' group: 7.45 ± 2.43). As such, follow-up results showed similar mean knowledge scores in both studied groups. Furthermore, RM-ANOVA results reported high statistical improvements with a large effect size in the study' group regarding both knowledge categories ($p < 0.001$). Compared with the controlled group results, non-significant differences were indicated at the three study times ($P = 0.066$ and $P = 0.098$, respectively).

Regarding total knowledge score, RM-ANOVA test demonstrated high statistical improvements in the total study group' knowledge mean score from baseline (23.62 ± 6.70) to immediate post-test (42.35 ± 3.24) and three months post-test follow up (40.27 ± 4.67) at ($P\text{-value} \leq 0.001$), in contrast to the control group results, which indicated insignificant differences at ($P\text{-value} = 0.246$), with minimal change of mean score from baseline (23.20 ± 6.17) to immediate post-test (23.75 ± 6.50) and three months post-test follow up (23.27 ± 6.57) at the three study' times.

Caregivers' reported practice categories scores towards the cerebral palsy:

Table (5) shows the distribution of caregivers' practices in both groups regarding hygienic care, motor disorders' care, and seizures' care at the three study phases. At the pre-test assessment, inadequate practice was demonstrated by both studied groups regarding all the previously mentioned categories. Compared to immediately after results, this inadequate mean score improved in the study' group but remained inadequate in the control group as follows: hygienic care (study' group: 3.45 ± 0.90 , and control group: 2.42 ± 1.08); motor disorders care (study' group: 3.75 ± 0.66 , and control group: 1.15 ± 1.40); and seizures' care (study' group: 9.22 ± 1.71 , and control group: 6.22 ± 1.57). Concerning follow-up results, an adequate level was reported in the study' group towards all the above-mentioned practice categories, compared to inadequate practice in the control group. Additionally, analysis of variance results of the study' group shows highly statistical differences

with a grand effect size regarding all previous reported practice categories ($p \leq 0.001$), compared with non-significant differences detected in the control group at the three study times ($P = 0.071$, $P = 0.164$, and $P = 0.365$, respectively).

Table (6) reveals the distribution of caregivers' practices in both groups towards playing and sports activities, and communication of children with others. At the baseline survey, inadequate levels of practice were reported by both studied groups regarding both practice categories. Compared to immediately after results, the study' group reported an adequate practice mean score, in contrast to the control group, which reported an inadequate mean score: playing and sports activities (study' group: 3.45 ± 0.90 , and control group: 2.42 ± 1.08); and communication with others (study' group: 3.75 ± 0.66 , and control group: 1.15 ± 1.40). As regards follow-up results, both studied groups showed similar mean practice scores. The analysis of variance test also reported high statistical differences with a high effect size in the study' group regarding both practice categories ($p \leq 0.001$). In the control group results, non-significant differences were reported at the three study times ($P = 0.06$, and $P = 0.06$, respectively).

As regard total practice score, the study' group demonstrated highly statistical differences at ($F = 129.9$, $P\text{-value} \leq 0.001$, $\eta^2 = 0.76$), in contrast to the control group results, which showed insignificant differences at ($F = 3.96$, $P\text{-value} = 0.054$, $\eta^2 = 0.09$) at the three study times.

CP Children's outcomes (quality of life and functional balance):

Table (7) demonstrates the mean scores of the quality of life (QOL) categories among both CP children groups. At baseline assessment, the independent t test showed similarity between the two CP children's QOL categories. After six months of package' implementation, the CP children in the study' group reported higher physical, emotional, social, and school functioning mean scores; these differences were statistically significant at ($P \leq 0.001$), while the children in the control group showed minimal changes regarding all QOL categories mean scores; these changes were statistically insignificant at ($P = 0.47$, $P = 0.67$, $P = 0.147$, and $P = 0.057$, respectively), as demonstrated by the paired t test.

Table (8) represents the comparison of the total quality of life (QOL) and pediatric functional balance (PFB) results between the two CP children groups. At the baseline assessment, the independent t test indicated similarity between the two CP children groups regarding QOL and PFB ($P = 0.061$ and $P = 0.434$, respectively). After three months of package' implementation, the children in the package group indicated significant improvement with a high effect size regarding QOL and PFB ($P\text{-value} \leq 0.001$), compared to the control group, which showed a non-significant result towards QOL and PFB ($P = 0.09$ and $P = 0.077$, respectively).

Table (1): Caregivers' Socio-demographic characteristics.

Items	Total number of caregivers =80				P- value Significance test
	study group N=(40)		Control group N=(40)		
	No.	%	No.	%	
Relationship with child					
Mother	32	80	36	90	0.299
Father	6	15	4	10	
Grandmother	2	5	00		
Age					
25- <35	16	40	17	42.5	0.344
35-<45	19	47.5	14	35	
-45 and More	5	12.5	9	22.5	
□(SD)	39.42(6.74)		40.90(7.12)		
Educational level					
Secondary	21	52.5	13	32.5	0.07
University	19	47.5	27	67.5	
Occupation					
Employee	6	15	4	10	0.514
Free work	17	42.5	14	35	
Not working/housewife	17	42.5	22	55	
Marital status					
Married	25	62.5	25	62.5	0.911
Divorce	11	27.5	12	30	
Widow	4	10	3	7.5	
Residence					
Urban	24	60	19	47.5	0.262
Rural	16	40	21	52.5	
Number of siblings					
One	17	42.5	18	45	0.776
Two	14	35	14	35	
Three	6	15	7	17.5	
Four	3	7.5	1	2.5	
Previous attendance of education/training about management of cerebral palsy					
No	28	70	32	80	0.302
Yes	12	30	8	20	

P value Significance * Significant ($p \leq 0.05$).

Table (2): Clinical profile of children with cerebral palsy

Clinical profile	Total number of CP children =80				Significance test
	study group N=(40)		Control group N=(40)		
	No.	%	No.	%	
Age					
4-<6ys	3	7.5	4	10	0.380
6-8ys	6	15	5	12.5	
8-10ys	12	30	19	47.5	
10-12ys	19	47.5	12	30	
□(SD)	9.25(2.59)		8.75(2.46)		
Gender					
Male	19	47.5	26	65	0.115
Female	21	52.5	14	35	
Ranking					
First	15	37.5	15	37.5	0.354
Second	16	40	19	47.5	
Third	6	15	6	15	
Above third	3	7.5	00	00	
Education					
Nursery	3	7.5	4	10	0.634
Primary	29	72.5	25	62.5	
Preparatory	8	20	11	27.5	
The main associated health problems of CP children					
Feeding problems	7	17.5	9	22.5	0.891
Behavior abnormalities	16	40	17	42.5	
Learning difficulties	10	25	10	25	
Motor	5	12.5	3	7.5	
Speech	2	5	1	2.5	
Family history of the CP disease					
No	23	57.5	28	70	0.245
Yes	17	42.5	12	30	

Significant ($p \leq 0.05$).

Table (3): Caregivers' knowledge regarding cerebral palsy (pre/ immediate post/ follow up)

Items	Caregivers No=80											
	study group N=(40)						Control group N=(40)					
	Pre		Immediate Post		After 3 months follow up		Pre		Immediate Post		After 3 months follow up	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Definition and the etiology score =(2)												
Poor	6	15	00	00	00	00	4	10	5	12.5	11	27.5
Average	23	57.5	9	22.5	12	30	29	72.5	24	60	20	50
Good	11	27.5	31	77.5	28	70	7	17.5	11	27.5	9	22.5
(SD)	1.25(0.64)		1.77(0.42)		1.70(0.46)		1.07(0.52)		1.15(0.62)		0.95(0.71)	
Significance test	F= 20.53		P-value≤0.001		η ² =0.345		F=3.029P-value =0.09		η ² =0.072			
Risk factors score=(14)												
Poor	34	85	00	00	00	00	37	92.5	32	80	34	85
Average	6	15	11	27.5	13	32.5	3	7.5	8	20	6	15
Good	00	00	29	72.5	27	67.5	00	00	00	00	00	00
□(SD)	2.95(1.07)		12.35(2.71)		11.97(2.96)		3.15(2.52)		3.35(3.17)		2.95(3.07)	
Significance test	F= 150.3		P-value≤0.001		η ² =0.79		F=3.39		P-value = 0.073		η ² =0.08	
Clinical presentation score=(8)												
Poor	12	30	00	00	00	00	12	30	10	25	12	30
Average	10	25	00	00	8	20	2	5	11	27.5	10	25
Good	18	45	40	100	32	80	26	65	19	47.5	18	45
□(SD)	4.70(3.00)		7.80(0.60)		6.82(1.41)		5.10(3.01)		4.85(2.87)		4.70(3.00)	
Significance test	F= 26.45		P-value≤0.001		η ² =0.40		F=3.89P-value = 0.056		η ² =0.091			
Investigation score=(3)												
Poor	5	12.5	00	00	00	00	9	22.5	9	22.5	6	15
Average	26	65	12	30	21	52.5	27	67.5	15	37.5	24	60
Good	9	22.5	28	70	19	47.5	4	10	16	40	10	25
□(SD)	2.10(0.59)		2.70(0.46)		2.47(0.50)		1.87(0.56)		2.17(0.78)		2.10(0.63)	
Significance test	F=14.34		P-value≤0.001		η ² =0.269		F= 3.92		P-value = 0.055		η ² =0.091	

Table (4): Caregivers knowledge regarding CP' management and signs of seizure (pre/ immediate post/ follow up), Cont

Items	Caregivers No=80											
	study group N=(40)						Control group N=(40)					
	Pre		Immediate Post		After 3 months follow up		Pre		Immediate Post		After 3 months follow up	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Management score=(8)												
Poor	10	25	00	00	00	00	10	25	10	25	10	25
Average	8	20	1	2.5	4	10	14	35	7	17.5	8	20
Good	22	55	39	97.5	36	90	16	40	23	57.5	22	55
(SD)	5.20(1.98)		7.72(0.64)		7.45(1.17)		4.92(1.83)		5.07(1.81)		5.20(1.98)	
Significance test	F= 42.61		P-value≤0.001		η ² =0.52		F= 3.58		P-value = 0.066		η ² =0.084	
Signs of seizures attack score=(10)												
Poor	8	20	00	00	00	00	11	27.5	8	20	8	20
Average	10	25	00	00	00	00	11	27.5	11	27.5	13	32.5
Good	22	55	40	100	40	100	18	45	21	52.5	19	47.5
□(SD)	7.55(2.49)		10.0(0.0)		9.87(0.33)		7.07(1.48)		7.45(2.43)		7.37(2.43)	
Significance test	F=35.99		P-value≤0.001		η ² =0.48		F= 2.86		P-value =0.098		η ² =0.068	
Total knowledge score=(45)												
Poor	18	45	00	00	00	00	18	45	17	42.5	18	45
Average	20	50	1	2.5	4	10	22	55	21	52.5	20	50
Good	2	5	39	97.5	36	90	00	00	2	5	2	5
(SD)	23.62(6.70)		42.35(3.24)		40.27(4.67)		23.20(6.17)		23.75(6.50)		23.27(6.57)	
Significance test	F= 185.44		P-value≤0.001		η ² =0.82		F=1.42		P-value =0.246		η ² =0.03	

F for repeated measure ANOVA, η²= partial eta squared (effect size of RM-ANOVA), P Significance * Significant (p≤ 0.05)

Table (5): Care givers reported practice regarding care of their children with cerebral palsy (pre/ immediate post/ follow up)

Items	Caregivers No=80											
	study group N=(40)						Control group N=(40)					
	Pre		Immediate Post		After 3months follow up		Pre		Immediate Post		After 3 months follow up	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Hygienic carescore=(4)												
Inadequate practice	30	75	11	27.5	19	47.5	32	80	27	67.5	30	75
Adequate practice	10	25	29	72.5	21	52.5	8	20	13	32.5	10	25
(SD)	2.4(1.03)		3.45(0.90)		3.05(1.01)		2.30(1.11)		2.42(1.08)		2.40(1.03)	
Significance test	F= 10.74P-value≤0.001				η ² =0.22		F= 2.73P-value =0.071				η ² =0.06	
Motor disorders care score=(4)												
Inadequate practice	34	85	5	12.5	7	17.5	36	90	33	82.5	33	82.5
Adequate practice	6	15	35	87.5	33	82.5	4	10	7	17.5	7	17.5
(SD)	0.85(1.35)		3.75(0.66)		3.65(0.76)		0.96(1.25)		1.15(1.40)		1.07(1.43)	
Significance test	F= 169.55P-value≤0.001				η ² =0.81		F= 1.85P-value =0.164				η ² =0.04	
Seizures' carescore=(10)												
Inadequate practice	12	30	4	10	8	20	14	35	12	30	12	30
Adequate practice	28	70	36	90	32	80	26	65	28	70	28	70
(SD)	6.00(1.32)		9.22(1.71)		8.40(2.28)		5.82(1.39)		6.22(1.57)		6.00(1.43)	
Significance test	F=35.97P-value≤0.001				η ² =0.48		F= 1.02P-value =0.365				η ² =0.02	

Table (6): Distribution of Care givers' reported practice towards CP children's playing , sports activities, and communication with others (pre/ immediate post/ follow up), Cont

Items	Caregivers No=80											
	Study group N=(40)						Control group N=(40)					
	Pre		Immediate Post		After 3 months follow up		Pre		Immediate Post		After 3 months follow up	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Playing and sports activities score=(8)												
Inadequate practice	27	67.5	3	7.5	4	10	25	62.5	19	47.5	21	52.5
Adequate practice	13	32.5	37	92.5	36	90	15	37.5	21	52.5	19	47.5
\bar{x} (SD)	3.97(2.17)		7.35(1.52)		6.45(1.94)		4.22(2.33)		4.75(3.01)		4.57(2.96)	
Significance test	F=41.98 P-value \leq 0.001			$\eta^2=0.51$			F=3.50 P-value =0.06 $\eta^2=0.08$					
Communication with others score=(6)												
Inadequate practice	34	85	13	32.5	24	60	37	92.5	37	92.5	37	92.5
Adequate practice	6	15	27	67.5	16	40	3	7.5	3	7.5	3	7.5
\bar{x} (SD)	1.27(1.82)		4.42(2.44)		3.60(2.27)		0.97(1.45)		1.25(1.61)		1.05(1.50)	
Significance test	F=29.05			P-value \leq 0.001			$\eta^2=0.42$			F= 2.17 P-value =0.12 $\eta^2=0.05$		
Total reported practice score=(32)												
Inadequate practice	33	82.5	3	7.5	4	10	31	77.5	29	72.5	31	77.5
Adequate practice	7	17.5	37	92.5	36	90	9	22.5	11	27.5	9	22.5
\bar{x} (SD)	14.50(4.60)		28.20(4.68)		25.15(5.17)		14.27(4.66)		15.55(5.34)		15.10(5.17)	
Significance test	F= 129.9 P-value \leq 0.001			$\eta^2=0.76$			F= 3.96 P-value =0.054 $\eta^2=0.09$					

N.P: F:RM- ANOVA, \bar{x} : Mean, **SD:** Standard deviation, η^2 : Partial Eta Squared (the effect size of RM-ANOVA), **P:** Significance. * Significant ($p \leq 0.05$)

Table (7): Comparison of the Quality of Life between the both Cerebral Palsy children studied groups before and after six months of the package's implementation

Items	CP Children No=80								Significance test between baseline data
	Study group N=(40)				Control group N=(40)				
	Pre		After 6 months		Pre		After 6 months		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Physical Functioning	16.30	1.28	17.58	1.36	15.87	1.20	15.95	1.25	t**=1.63P=0.105
Significance test	t*=17.19P-value≤0.001 d=0.96				t*=0.72P=0.47d=0.06				
Emotional Functioning	11.80	1.26	15.43	1.27	12.07	1.02	12.15	1.33	t**=0.980 P= 0.33
Significance test	t*=57.15P-value≤0.001 d=2.88				t*=0.42P=0.67 d=0.067				
Social Functioning	11.60	1.21	14.80	1.18	11.20	0.93	11.37	1.14	t**=1.58 P=0.117
Significance test	t*=33.30P-value≤0.001 d=2.68				t*=1.48P= 0.147d=0.16				
School Functioning	11.42	1.29	12.22	0.94	10.95	0.78	11.10	0.87	t**= 1.24 P=0.217
Significance test	t*=12.02P-value≤0.001 d=0.70				t*=1.96P=0.057 d=0.18				

N.P: t*: Independent t-test,t**: Paired t test,d: Effect size of t tests (Cohen's d)d<0.2 small, d=0.5 medium, d>0.8 large,**P** Significance * Significant (p≤ 0.05).

Table (8): Comparison of the total Quality of Life and functional balance between the both Cerebral Palsy children study groups before and after six months of the package's implementation

Items	CP Children No=80								Significance test between baseline data
	Study group N=(40)				Control group N=(40)				
	Pre		After 6 months		Pre		After 6 months		
	No.	%	No.	%	No.	%	No.	%	
Total Quality of Life score=(100)									
Low	35	87.5	00	00	37	92.5	00	00	t**=1.90 P=0.061
Moderate	5	12.5	38	95	3	7.5	34	85	
High	00	00	2	5	00	00	6	15	
□(SD)	51.12 (2.55)		60.04 (2.50)		50.10 (2.26)		50.57 (2.90)		
Significance test	t*=52.74 P-value≤0.001 d=3.50				t*=1.71 P=0.09 d=0.18				
Total functional balancescore=(56)									
□(SD)	39.82(2.12)		50.61(2.05)		40.25(2.02)		40.50(2.16)		t**=0.787
Significance test	t*=163.06P-value≤0.001 d=5.17				t*=1.81P=0.077 d=0.12				P= 0.434

t**: Independent t-test,t*: Paired t test,d: Effect size of t tests (Cohen's d)d<0.2 small, d=0.5 medium, d>0.8 large,P Significance * Significant (p≤ 0.05).

Discussion:

Children with cerebral palsy (CP) need multifaceted care as they suffer from several associated health problems, such as sensory, intellectual, communicative, and motor function impairments. Nonetheless, the caregiver plays a crucial role, namely in providing their children with healthcare. As a result, any caregiver for a child with cerebral palsy needs to be highly confident in her abilities as well as possess the necessary information and abilities. In order to improve the quality of life (QoL) for CP children and their caregivers, multifaceted education can help them deal with and manage issues related to their CP. In order to suit their demands, it also gives them the chance to develop new talents while improving their current skills and competencies. Therefore, this experiment assessed how a caregiver-centered package affected the functional balance and daily living activities of children with cerebral palsy.

Regarding the Scio-demographic and clinical characteristics, similarity-determining tests indicate homogeneity in all the studied characteristics between the study and control groups of the caregivers and their CP children who participated in the baseline survey, as Chi square and t tests showed insignificant differences ($P>0.05$). This similarity is the basic requisite for any randomized controlled trial to be more confident that the observed differences in outcomes between the groups are related to the intervention rather than confounding factors. This finding is supported by randomized trial conducted by Nobakht, Rassafiani, Hosseini, & Hosseinzadeh (2020), who reported the similarity of the baseline

characteristics between the interventional and control groups.

With regard to the caregivers' prior attendance at educational programs or training for the management of cerebral palsy, it was discovered that a greater proportion of them had never attended any prior educational programs regarding cerebral palsy. The RCT of Kahjoogh et al. (2019), which examined the "Randomized controlled trial of occupational performance coaching for mothers of children with cerebral palsy," and which found that mothers of CP children lacked knowledge of and access to CP training programs, is also compatible with this conclusion. The researcher may be able to explain the current findings in light of the fact that nurses may not have had enough time to learn and acquire the necessary skills to provide caregiver education due to staff shortages and workload.

According to caregivers' Scio-demographic characteristics, the mean age of both study groups was nearly 40 years old; nearly half of them were housewives, two-thirds of them were married and A large percentage of caregivers lived in urban areas. These current results may be due to the place of study is a university hospital located in Mansoura, so most of those who come to it are from urban areas. These results are compatible with the study conducted by Draz & Elsharkawy (2021), who performed a quasi-experimental study on 50 mothers of children with CP recruited from pediatric hospital at Ain Shams University and revealed that "the mean age of the studied mothers was 47.2 ± 8.2 years, more than two fifth of them had middle education, slightly more than half of them were

housewives and nearly three quarters of mothers were residing in urban areas.”

As regard the clinical profile of the studied CP children, the mean age of CP children was nine years in both groups; slightly more than half of children in the study and more than one third of them in the control groups were females who studied at the primary level; besides, they were the second children. A large percentage of them suffer from behavior abnormalities and have a family history of cerebral palsy. The current findings might be explained by the researcher in the light of the evidence that cerebral palsy can be a hereditary disease in one tenth of all cases, as revealed by genetic testing. These findings matched the study done by Sayed, Abdel monem& Ahmed (2021), who reported that “mean age of CP children was 7.3 ± 3.4 years, and more than half of them were females. Related to educational level, nearly one thirds of studied children were at primary school.

Caregivers’ knowledge in the current trial shows high statistical improvements in the package group ($P\text{-value} \leq 0.001$) regarding cerebral palsy definition, etiology, risk factors, investigations, seizure signs, and management of it. Compared to the control group results, which indicated insignificant differences ($P\text{-value} > 0.05$) regarding all mentioned knowledge categories at the three study phases. Regarding total knowledge score, the current trial also shows high statistical differences in the package group ($P\text{-value} \leq 0.001$) with huge effect size ($\eta^2 = 0.82$), compared to the control group results, which indicated insignificant differences ($P\text{-value} = 0.246$) at the three study times. These results may be due to using different teaching methods

such as group discussion, lectures, and role-playing. In addition, various assisted educational materials, such as pamphlets and guiding booklets, contain all the content of the educational intervention.

These results supported the study performed by Baraka, El-Sayed, Elshahawy, & Farag (2022), who conducted the study on 60 mothers with their CP children and concluded that their educational program, positively impacted the CP's parental knowledge. Also, Rao et al. (2019) cited in their systematic review that health education interventions positively increase mothers' awareness. A similar finding was revealed by Draz& Elsharkawy (2021), who conducted a quasi-experimental study on 50 caregivers and concluded that “supportive educational program for mothers regarding the care of their female adolescents with cerebral palsy had a positive effect on their knowledge and reported practice.”

Regarding total reported practice score, the package group demonstrated highly statistical differences at ($P \leq 0.001$) with a grand effect size ($\eta^2 = 0.76$), in contrast to the control group results, which showed insignificant differences at ($P = 0.054$) throughout the three study phases. These results were explained as the researchers used illustrative methods such as videos and photos during program sessions, developed teaching materials based on the initial needs assessment of the caregivers and employed straightforward communication techniques. These results agree with the findings of Sayed et al. (2021), who cited that the empowerment program for caregivers has a beneficial effect on improving their practices regarding the care of their CP children,

with positive consequences for both child and caregiver. Also, it is supported by Rashad, EL-Dakhakhny, AbdElsalam& Mohamed (2021), who conducted a training program on 50 mothers and concluded that the educational intervention had a positive effect on improving the mothers' practices about the care of their CP children, as there was a statistically significant difference throughout the three phases of the study. These findings support the current research hypotheses.

Concerning quality of life (QOL) of CP children after six months of package implementation, the children in the package group indicated significant differences with a huge effect size regarding QOL ($P \leq 0.001$), compared to the control group, who showed an insignificant result towards QOL ($P = 0.09$). These results may be due to the multifaceted intervention, as the educational package may improve the relationship between caregivers and their CP child, which improves emotional and social function and consequently positively impacts physical and school functioning.

These findings were consistent with research by Sayed et al. (2021) which found that caregivers of CP children benefited from an empowerment program that raised the children's quality of life. In a similar vein, Nobakht et al. (2020) said that "the study group's mean scores of total QOL scores post-intervention were higher than the control group." Furthermore, this aligns with the findings of the Baraka et al. (2022) study, which stated that "children with cerebral palsy and their families have a negative impact on their quality of life" and came to the conclusion that the

educational program that caregivers received had a major impact on the quality of life of their children.

In relation to pediatric functional balance (PFB) after six months of package implementation, the children in the package group demonstrated significant improvement with a high effect size regarding PFB ($P\text{-value} \leq 0.001$), in contrast to the control group, which indicated a non-significant score towards PFB at ($P = 0.077$). This finding is supported by the systematic review of Zai, Xu, Wu, Wang, & Wang (2022), who concluded that "the task-oriented training could effectively improve gross motor function, balance, and activities of daily living in children with CP." In addition, it is consistent with the repeated-measures experiment of Ahmed et al. (2023), who reported in their study that their intervention had positive effects on gross motor function and functional balance in a child with CP. These findings also support the trial hypotheses related to the CP children's outcomes.

Conclusion and recommendations:

Conclusion:

The educational package demonstrated a significant improvement in knowledge and practice regarding cerebral palsy among the caregivers in the package group, compared to the non-significant effect on the control group. Additionally, the educational package had a positive effect on the quality of life and functional balance of the CP children in the study' group, compared to the non-significant differences among the children in the control group.

Recommendation:

Developing and implementing an educational initiative for mothers regarding care of their children with CP continuously. Moreover, replication of the research on large sample for generalization as well as further researches are required to enhance children with CP clinical outcomes

References

- Ahmed, S., Khalil, A., & AbouZeid, M.I. (2023). Effect of an educational program about cerebral palsy management on mothers' performance. *Port Said Scientific Journal of Nursing*, 10(1), 59–79.
- Ajayi, O. O., Fatudimu, M. B., & Hamzat, T. K. (2022). Effects of an educational programme on knowledge of cerebral palsy among informal caregivers of children presenting at selected physiotherapy clinics in Ibadan. *European Journal of Medical and Health Sciences*, 4(2), 57–62.
- Ansa, O. E. O., Mprah, K. W., Moses, M. O., Owusu, I., & Acheampong, E. (2021). Effect of Community-Based Functional Aerobic Training on Motor Performance and Quality of Life of Children with Spastic Cerebral Palsy. *Ethiopian journal of health sciences*, 31(2), 381–392.
- Baiee, Z. A., K, AL-Doori, N., M & Hassan, A. A. (2019). Mother's Knowledge Towards their Children with Cerebral Palsy in Babylon Province, *Indian Journal of Public Health Research & Development*, 10(10), 3898- 3903.
- Baraka, N.I., El-Sayed, E.M., ELShahawy, A.K., & Farag, N.H. (2019). Effect of Educational Intervention Program on Mothers, Knowledge and Practice about Quality of Life for Their Children with Cerebral Palsy. *IOSR Journal of Nursing and Health Science*, 8(2), 43-52.
- Davis, E., Davern, M., Waters, E., Boyd, R., Reddihough, D., Mackinnon, A., & Graham, H.K. (2013). *Cerebral Palsy Quality of Life Questionnaire for Adolescents (CP QOL-Teen) Manual*. Melbourne, University of Melbourne.
- Fejes, M., Beatrix, V., & Katalin, H. (2019). Children and adolescents with cerebral palsy have reliable knowledge about their own condition - self- and parent reported quality of life.
- Franjoine, M., Gunther, J. & Taylor, M. (2003). Pediatric Balance Scale: a modified version of the Berg Balance Scale for the school-age child with mild to moderate motor impairment. *Pediatric Physical Therapy*, 15, 114-128.
- Gad, S. A., Khalil, A., & Abouzeid, M. (2023). Effect of an educational program about cerebral palsy management on mothers' performance. *Port Said Scientific Journal of Nursing*, 10(1), 59-79.
- Gutenbrunner, C. & Nugraha, B. (2017). Principles of Assessment of Rehabilitation Services in Health Systems: Learning from experiences. *Journal of rehabilitation medicine*, 50.
- Gutenbrunner, C., & Nugraha B. (2018). Responding to the World Health Organization Global Disability Action Plan in Egypt: A Technical Consultation to Develop a National Disability, Health and Rehabilitation Plan. *J Rehabil Med*, 50, 333–337.
- Hashem, S. F., & Abd El Aziz, M.A. (2018). The effect of an educational intervention for improving mothers' care for their children with cerebral palsy. *International*

- Journal of Nursing Didactics, 08(04), 10–20.
- Kahjoogh, A.M., Kessler, D., Hosseini, S.A. (2019). Randomized controlled trial of occupational performance coaching for mothers of children with cerebral palsy. *British Journal of Occupational Therapy*. 2019;82(4):213-219. doi:10.1177/0308022618799944
- Kim, D. J., & Kim, Y. J. (2019). Effects of the Parenting Efficacy Improvement Program for mothers as primary caregivers of children with cerebral palsy under rehabilitation. *Journal of exercise rehabilitation*, 15(6), 763–768.
- Larsen, M.L., Rackauskaite G., Greisen G., Laursen B., Uldall P., Krebs L., Høi-Hansen C.E. (2021). Declining prevalence of cerebral palsy in children born at term in Denmark. *Dev. Med. Child. Neurol.* 64, 715–722.
- Lei, Y., Lam, C. & Lam, M. et al. (2017). Validity and Reliability of Timed Up and Go Test on Dynamic Balance in 3-5 Years Old Preschool Children. *Journal of Yoga and Physical Therapy*, 7 (2), 266.
- Mushta, S. M., King, C., Goldsmith, S., Smithers-Sheedy, H., Badahdah, A., Rashid, H. & McIntyre, S. (2022). Epidemiology of Cerebral Palsy among Children and Adolescents in Arabic-speaking countries: A systematic review and meta-analysis. *Brain Sciences*, 12(7), 859.
- Sayed, M.A, Abdelmonem, H.H, & Ahmed, FA.. (2021). Effect of empowerment program for caregivers on quality life of children with cerebral palsy. *Egyptian Journal of Health Care*, 12(1), 140–155.
- Zuurmond, M., O'Banion, D., Gladstone, M., Carsamar, S., Kerac, M., & Baltussen, M., et al. (2018). Evaluating the impact of a community-based parent training program for children with cerebral palsy in Ghana. *PLoS ONE*, 13(9), e0202096.