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ORIGINAL ARTICLE

Examining mobility, independence, motor function, participation, and parental stress in a school-aged Turkish cerebral palsy population: a cross-sectional study

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Abstract

Aims This study aimed to describe a school-aged Turkish cerebral palsy (CP) population in terms of gross motor function, mobility, independence, and participation, and to investigate parental stress.

Methods Mobility (Functional Mobility Scale (FMS)), independence (Barthel Index (BI)), motor function (Gross Motor Function Measurement (GMFM)), functional classification (Gross Motor Function Classification System (GMFCS)), participation (Pediatric Outcome Data Collection Instrument (PODCI)), and parents' stress (Parental Stress Scale (PSS)) of 100 school-aged children with CP aged 5–15 years old were evaluated. School-related difficulties and restrictions were also questioned.

Results Of the 100 children with GMFCS levels I–V, almost half had independent mobility on level or all surfaces according to the FMS, with a relatively high GMFM score (72.8%), and above average BI (12 from 20), and PODCI Global Functioning (62.8%) scores. Strong-to-very strong correlations were determined between all test batteries. A mean score of 42.3 ± 9.92 out of 90 was obtained for parental stress with a weak correlation to the GMFCS and the child's mobility distance according to family ($p < 0.05$).

Conclusions Turkish school-aged children with CP displayed functional abilities that are above average besides experiencing restrictions in the school environment. Parents' view on the physical condition of the school varied depending on functional and mobility levels of their children.

Keywords Cerebral palsy · Mobility · Participation · School · Motor function

Introduction

Cerebral palsy (CP) is a well-known, permanent neurodevelopmental disorder caused by damage to the developing brain. The damage leads to physical disabilities concerning motor impairment, which places limitations on activity and participation, and causes sensory, cognitive, communication, and behavioral problems throughout the lifespan [1–3]. The problems caused by CP relate to neurologic and musculoskeletal systems, and the severity of motor impairments and their influence on the child's functions vary in each case. While some of the patients can walk independently with or without a mobility device in the community, other patients require a cordless wheelchair, and some depend on the assistance of a caregiver for transfers and self-care in their daily routine [4, 5]. Significant differences are also evident among the children who are able to walk in terms of speed, distance, endurance, and the need for assistive devices [6].

Participation of children with CP is reported to be affected by many factors besides mobility levels and environmental settings, such as pain, psychological problems, and parental stress. These multi-factorial effects on participation lead to different degrees of restrictions in the daily life of the individuals such as performing leisure activities, enacting social roles, and receiving education with their peers [5, 7–10].

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Many recent studies on the lifelong neuroplasticity of the brain have shown the positive effects of some neurorehabilitative treatment techniques combined with behavioral interventions for the structural and functional reorganization of the cortex with new synaptic formations between cortical areas. While no treatment method has been developed yet that can completely cure brain damage, some physical and occupational therapy interventions have been reported to decrease the disability level associated with motor impairment and improve functional abilities and quality of life with changes in neuronal excitability of the injured brain [11–16]. The aforementioned neurodevelopment, which is supported by activity-based rehabilitation approaches, is aimed to increase the motor skills, functional independence, and quality of life of children with CP, and thus increase the integration of children with CP by creating opportunities to promote their education and social roles [3].

Therefore, the aims of this study are to (a) describe the gross motor function, mobility, independence, and participation of a school-aged Turkish CP population; (b) demonstrate the interrelations between different functional assessments and determine the associations between school-related factors and functional measures; and (c) investigate parental stress among the parents of this population.

Materials and methods

Participants

The study recruited 100 children with unilateral or bilateral spastic CP, who were aged 5–15 years, attending school (private/government schools, special education institutions) daily and living in Istanbul city, which has the highest population in Turkey. Informed consent was obtained from all individual participants included in the study.

Children with severe neurological (patients with epilepsy seizures that cannot be controlled with medication), visual, and/or auditory problems, who had undergone an orthopedic surgery within the last 6 months, and who had serious cooperation problems that imposed barriers to assessments were excluded from the study.

Measures

The age (year), Gross Motor Function Classification System (GMFCS) level (indicating the severity of motor function) [17], usage of an orthotic device, and parent/child responses to the specific school-related questionnaire created by study team were obtained from each participating child. The following assessments were then applied:

Assessment of functional mobility The Functional Mobility Scale (FMS) was used to assess the functional mobility levels of the children recruited to the study. The scale, developed by Graham et al. (2004), was determined a reliable and valid performance measurement to classify the functional mobility of children with CP aged 4–18 years [18, 19]. The children are classified based on their walking ability and need for assistive devices at three different distances: 5 m, 50 m, and 500 m. To determine the level of mobility at each distance, values from 1 (uses wheelchair) to 6 (independent on all surfaces) are given according to the child's need for assistance.

Assessment of motor function The motor functions of children included in the study were assessed using the Gross Motor Function Measure-88 (GMFM-88), which is a well-known standardized observational test designed to measure changes in gross motor functions over time in children with CP. The GMFM includes five main dimensions from A (lying and rolling) to E (walking, running, and stair climbing), comprising 88 items. The GMFM takes 40 to 60 min to score the patients' movements. The items are scored from 0 (unable to start the movement) to 3 (completes the movement independently). The total GMFM score is obtained by dividing the sum scores of the dimensions (A–E) by five. Higher scores indicate higher levels of motor skills [20, 21].

Assessment of functional Independence in daily activities The level of independence in self-care activities of children included in the study was examined by using the Barthel Index (BI). The BI was developed in 1988 to determine the level of independence of individuals over the age of 5. The BI evaluates independence for 10 sub-domains of daily activities such as bowels, bladder, grooming, dressing, mobility, with a scoring system ranging from 0 (dependent) to 2 (independent), giving a total score of 20. Higher scores indicate higher levels of independence by the individual in daily activities [22–25].

Assessment of participation The Pediatric Outcome Data Collection Instrument (PODCI) is widely used to evaluate the functional health status and quality of life of children as well as activity and participation restrictions. It is a comprehensive and easy to complete test developed for individuals with CP aged 2–18 years. The clear statements of this instrument allow for family-report or self-report evaluations based on function and quality of life. The instrument has five subscales comprising 86 items. Items are scored ranging from 0 to 3 and 0 to 6. The subscales are formed under the following categories: the upper extremity function, transfer and basic mobility, sports and physical function, comfort/pain, and happiness-satisfaction. Total scores can be calculated between 0 and 100 to show the patient's global function which lower scores indicate a higher disability level. The current study used the Turkish version, which was shown to be valid and reliable for assessing activity limitations and participation of children with CP [26–29].

Assessment of parental stress The Parental Stress Scale (PSS) was used to evaluate the perceived parenting stress levels of the parents of the children with CP participating in the study. The scale uses 18 items to measure parenting stress, considering the effects of children on the parental role and avoiding confusion with general stress. The items are scored using a five point-Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). A total score ranging from 18 to 90 is achieved by summing the sub-scores of the four main domains: rewards, loss of control, stressors, and satisfaction. Higher scores indicate higher levels of parenting stress. This scale was recently shown to have adequate psychometric properties in families with chronic health conditions [30, 31].

Procedure

The assessments were carried out in the schools of participants in guidance of their parents after getting permission from the authorities of the schools and parents.

Data analysis

Statistical analysis was performed by using a Windows-based statistical analysis program, SPSS (Statistical Package for the Social Sciences). Descriptive statistics were identified using minimum (min), maximum (max), mean (X), and standard deviations for the quantitative data, and number (*n*) and percentage (%) values for the qualitative data. Normality tests were performed for all data sets by using the Kolmogorov-Smirnov test. The Spearman Correlation Coefficient (*r*) was used to determine the relations between test parameters in non-parametric test conditions because the data collected in this study did not comply with the normal distribution. Based on the guide that Evans (1996) suggested for the value of *r*, the strengths of the correlations were determined as follows: $r = 0.00–0.19$ indicates a very weak correlation, $r = 0.20–0.39$ is weak, $r = 0.40–0.59$ is moderate, $r = 0.60–0.79$ is strong, and $r = 0.80–1.00$ is a very strong correlation [32].

Results

In total, 100 school-aged children with spastic CP (19 unilateral with a mean age 9.3 ± 3.25 years, 81 bilateral with a mean age 8.5 ± 2.86 years) were recruited to participate in the study. The children were aged 5–15, with a mean of 8.64 ± 2.94 years. Of the children, 39 were at level I (7 unilateral CP, 32 bilateral CP), 17 were at level II (4 unilateral, 13 bilateral CP), six were at level III (2 unilateral, 4 bilateral CP), three were at level IV (all bilateral CP), and 35 were at level V (6 unilateral, 29 bilateral CP) of the GMFCS.

Table 1 shows the distribution of children according to a school-related questionnaire, including the child's orthotic usage and mobility distance, and physical conditions of the school based on the GMFCS levels.

Table 2 demonstrates functional mobility levels of the children, which were assessed using the FMS at 5 m, 50 m, and 500 m.

Table 3 presents the results related to motor functions (GMFM), independence (BI), and participation level (PODCI) of the school-aged Turkish children with CP and to the parental stress (PSS) of their families.

Tables 4 and 5 indicate the associations between the different measures, and the associations between the school-related questionnaire and other measures according to the Spearman's Correlation Coefficient.

No association was found between parenting stress and any of the other measures of the school-aged children with CP other than the GMFCS ($r = 0.238$, $p = 0.017$). A negative, weak, and statistically significant correlation was found between parental stress and the child's mobility distance according to the parent ($r = -0.233$, $p = 0.020$).

Discussion

Education is not only a right but it is also essential for all individuals. However, children with different kinds of disabilities have difficulties in many aspects of their daily life, including performing their social roles and functional abilities sufficiently well to access education and participate in a social and community life. Various factors that have been identified as barriers to participation for children with CP include limited functional motor abilities, low levels of independence in daily activities, challenging environmental settings, and limitations in their cognitive, behavioral, and emotional status [33–36]. This cross-sectional study was performed to obtain a functional description of a Turkish CP population of children aged 5–15 years who had access to education. The children were recruited from multi-centers such as government schools, where they receive their education with their healthy peers, private schools, which have more appropriate environmental settings, and schools for children with different kinds of disabilities. The population was recruited from the most populated, complex, and cosmopolitan city of Turkey, which has many advantages (with many well-organized rehabilitation clinics, social facilities, etc.) and disadvantages for disabled individuals.

Most of the school-aged children (56 of the subjects) included in this study were in levels I and II of the GMFCS, which supports evidence that the children with better functional abilities have the most opportunities to participate in daily

Table 1 Distribution of the children according to an assessment questionnaire including school-related questions based on the Gross Motor Function Classification System (*n* = 100)

	GMFCS levels*				
	Level I *n* (%)	Level II *n* (%)	Level III *n* (%)	Level IV *n* (%)	Level V *n* (%)
Usage of orthotic device (*n* = 97)					
Yes	14 (35.9)	12 (70.6)	4 (66.7)	3 (100)	19 (54.3)
No	25 (64.1)	5 (29.4)	1 (16.7)	–	16 (45.7)
Mobility distance according to parent (*n* = 100)					
Inside	10 (25.6)	7 (41.2)	5 (83.3)	–	26 (74.3)
Around home	11 (28.2)	8 (47.1)	1 (16.7)	1 (33.3)	8 (22.9)
Around school	12 (30.8)	2 (11.8)	–	2 (66.7)	1 (2.9)
Further distances	6 (15.4)	–	–	–	–
Whether the physical conditions of the school limit the child's mobility according to parent (*n* = 100)					
Limit	8 (20.5)	7 (41.2)	5 (83.3)	2 (66.7)	17 (48.6)
Does not limit	31 (79.5)	10 (58.8)	1 (16.7)	1 (33.3)	18 (51.4)
Time spent in school (*n* = 100)					
Less than 4 h	6 (15.4)	5 (29.4)	3 (50.0)	–	22 (62.9)
Part time	31 (79.5)	11 (64.7)	2 (33.3)	1 (33.3)	10 (28.6)
Full time	2 (5.1)	1 (5.9	1 (16.7)	2 (66.7)	3 (8.6)
Whether the child has physical difficulty at school (*n* = 100)					
Experiences physical difficulty	15 (38.5)	12 (70.6)	3 (50.0)	–	24 (68.6)
Does not experience physical difficulty	24 (61.5)	5 (29.4)	3 (50.0)	3 (100)	11 (31.4)
The level of the need of support in school toilet (*n* = 73)					
Fully dependent to another person	6 (18.2)	3 (21.4)	2 (66.7)	3 (100)	13 (65.0)
Partially needs another person	5 (15.2)	6 (42.9)	1 (33.3)	–	7 (35.0)
Fully independent	22 (66.7)	5 (35.7)	–	–	–

*GMFCS: Gross Motor Function Classification System

life and perform their roles as students in the community [33–36]. However, a considerable number of children (44 of the subjects) in levels III–V were still able to attend school, which shows that most parents are aware of the importance of education and school attendance for their children.

Previous studies have examined the functional mobility in CP populations, which refers to their mobility performance within environmental settings such as the home, school, and community. An agreement was found between clinician and parent reports of FMS [18, 37]. In this study,

Table 2 Functional mobility of the school-aged children included in the study

Functional Mobility Scale	Unilateral CP (*n* = 19)			Bilateral CP (*n* = 81)			Total (*n* = 100)		
	5 m* *n* (%)	50 m* *n* (%)	500 m* *n* (%)	5 m* *n* (%)	50 m* *n* (%)	500 m* *n* (%)	5 m* *n* (%)	50 m* *n* (%)	500 m* *n* (%)
N (does not apply)	–	–	2 (10.5)	9 (11.1)	9 (11.1)	13 (16)	9 (9)	9 (9)	15 (15)
C (crawling)	–	–	–	–	–	–	–	–	–
1 (uses wheelchair)	6 (31.6)	6 (31.6)	6 (31.6)	21 (25.9)	24 (29.6)	22 (27.2)	27 (27)	30 (30)	28 (28)
2 (uses a walker or frame)	1 (5.3)	4 (21.1)	2 (10.5)	3 (3.7)	1 (1.2)	4 (4.9)	4 (4)	5 (5)	6 (6)
3 (uses crutches)	–	–	–	1 (1.2)	–	–	1 (1)	–	–
4 (uses sticks—one or two)	–	–	–	–	–	–	–	–	–
5 (independent on level surfaces)	3 (15.8)	3 (15.8)	6 (31.6)	14 (17.3)	26 (32.1)	28 (34.6)	17 (17)	29 (29)	34 (34)
6 (independent on all surfaces)	9 (47.4)	6 (31.6)	3 (15.8)	33 (40.7)	21 (25.9)	14 (17.3)	42 (42)	27 (27)	17 (17)

*m = meter

Table 3 Functional assessment results of the children and parental stress ($n = 100$)

	Unilateral CP ($n = 19$)		Bilateral CP ($n = 81$)		Total ($n = 100$)	
	Minimum-maximum	X ± SD	Minimum-maximum	X ± SD	Minimum-maximum	X ± SD
Gross Motor Function Measure						
Lying and rolling	41.18–100	96.2 ± 13.45	3.92–100	86.5 ± 27.47	3.92–100	88.3 ± 25.64
Sitting	93.33–100	98.8 ± 2.16	0–100	79.6 ± 31.29	0–100	83.2 ± 29.15
Crawling and kneeling	52.38–100	93.9 ± 11.37	0–100	64.8 ± 36.83	0–100	70.3 ± 35.37
Standing	53.85–100	87 ± 13.66	0–100	46.3 ± 39.48	0–100	54.1 ± 39.38
Walking, running, and jumping	8.75–100	84.5 ± 20.49	0–100	41.3 ± 39.27	0–100	49.6 ± 40.17
Total	73.74–100	91.8 ± 7.92	14.19–100	68.3 ± 24.38	14.19–100	72.8 ± 24.03
Barthel Index (0–20)	10–20	14.7 ± 3.53	2–20	12.2 ± 5.6	2–20	12.6 ± 5.35
Pediatric Outcomes Data Collection Instrument (0–100)						
Upper extremity	50–100	84.2 ± 13.82	0–100	59.7 ± 32.37	0–100	64.4 ± 31.22
Transfers-Mobility	33–100	69.8 ± 28.11	0–100	57.4 ± 37.07	0–100	59.7 ± 35.80
Sports-Physical Function	12–58	28.1 ± 20.03	0–100	38.5 ± 31.12	0–100	36.6 ± 29.63
Comfort/Pain	7–100	91 ± 22.66	7–100	84.1 ± 22.84	7–100	85.4 ± 22.86
Global Functioning	44–97	71.5 ± 18.59	16–100	60.6 ± 23.86	16–100	62.6 ± 23.28
Happiness	0–100	53.6 ± 31.38	10–100	69.1 ± 26.94	0–100	65.8 ± 28.47
Parental Stress Scale (18–90)	20–67	43.5 ± 14.12	25–64	42.1 ± 8.75	20–67	42.3 ± 9.92

the FMS was scored based on parent declaration to determine the assistance required at three distances, and almost half of the patients were independent on level or all surfaces at 5 m and 500 m, and almost one-third were independent at 50 m. For 15% of the study population, the FMS at 500 m was not applicable, which can be negligible. The distribution of the population in terms of the need for assistance for mobility presents a satisfying view because almost half of the patients have their independence even at further distances, which correspond to school and community environments.

The functional status of the study population measured using GMFM can be considered particularly high at 72.8%, with a moderate independence level (12 points out of 20) measured using the BI. A total score of 62.6 out of 100 was obtained from activity limitation and participation measurement instrument in this study (PODCI), which was above average. This score indicates the school-aged Turkish CP population had a good level of participation in the community despite having remarkable physical restrictions measured by the "sports and physical function" dimension of the PODCI (36.6 out of 100). Examining the strong associations between the FMS, GMFM, GMFCS, BI, and PODCI, it can be commented that mobility, motor functions, and levels of participation are highly engaged to each other in this population. Considering that the ultimate goal for these children is to ensure that they benefit the same opportunities as their

Table 4 Associations between functional assessments based on Spearman's correlation coefficient

	FMS-5	FMS-50	FMS-500	GMFCS	GMFM	BI	PODCI-GF
FMS-5	1.00			− 0.902*	0.888 *	0.786*	0.751*
FMS-50		1.00		− 0.893*	0.862*	0.812*	0.765 *
FMS-500			1.00	− 0.851 *	0.821 *	0.759*	0.709 *
GMFCS				1.00	− 0.841*	− 0.709*	− 0.663*
GMFM					1.00	0.821*	0.754*
BI						1.00	0.840*
PODCI							1.00

*$p < 0.001$

FMS-5 = Functional Mobility Scale-5 m, FMS-50 = Functional Mobility Scale-50 m, FMS-500 = Functional Mobility Scale-500 m, GMFCS = Gross Motor Function Classification Scale, GMFM = Gross Motor Function Measure, BI=Barthel Index, PODCI-GF=Pediatric Outcomes Data Collection Instrument-Global Functioning

Table 5 The associations between functional measures and school-related questions

	FMS-5 *r* (*p*)	FMS-50 *r* (*p*)	FMS-500 *r* (*p*)	GMFCS *r* (*p*)	GMFM *r* (*p*)	BI *r* (*p*)	PODCI-GF *r* (*p*)
Usage of orthotic device	0.146 (0.147)	0.213 (*0.034*)	0.283 (*0.004*)	−0.168 (0.094)	0.197 (*0.049*)	0.067 (0.510)	0.185 (0.067)
Child's mobility distance according to parent	0.436 (*0.000*)	0.473 (*0.000*)	0.429 (*0.000*)	−0.484 (*0.000*)	0.593 (*0.000*)	0.566 (*0.000*)	0.513 (*0.000*)
Whether the physical conditions of the school limit the child's mobility according to parent	−0.269 (*0.007*)	−0.351 (*0.000*)	−0.260 (*0.009*)	0.273 (*0.006*)	−0.258 (*0.009*)	−0.162 (0.112)	−0.103 (0.308)
Time spent in school	0.374 (*0.000*)	0.382 (*0.000*)	0.386 (*0.000*)	−0.324 (*0.001*)	0.399 (*0.000*)	0.457 (*0.000*)	0.553 (*0.000*)
Whether the child has physical difficulty at school	−0.231 (*0.021*)	−0.163 (0.104)	−0.049 (0.628)	0.235 (*0.019*)	−0.267 (*0.007*)	−0.171 (0.092)	−0.128 (0.227)
The level of the need of support in school toilet	0.292 (*0.012*)	0.258 (*0.028*)	0.320 (*0.006*)	−0.264 (*0.024*)	0.341 (*0.003*)	0.466 (*0.000*)	0.341 (*0.003*)

FMS-5 = Functional Mobility Scale-5 m, FMS-50 = Functional Mobility Scale-50 m, FMS-500 = Functional Mobility Scale-500 m, GMFCS = Gross Motor Function Classification Scale, GMFM = Gross Motor Function Measure, BI=Barthel Index, PODCI-GF=Pediatric Outcomes Data Collection Instrument-Global Functioning

The italic numbers identifies the significance level as $p < 0.05$

healthy peers, with the optimum level of independence, the importance of physical and occupational approaches to enhance the motor functions becomes more important.

Most of the children with bilateral CP (81 of the study population) were using an orthotic device, which may help their ambulation or transfers in daily life or aid their alignment of the joints, except for children in GMFCS Level I. As seen in Table 5, the usage of orthotic devices has a very weak relation with functional mobility at 50 m and 500 m and motor function. Although it is known that mobility-assisting devices, such as wheelchairs and crutches, and appropriate environmental modifications are essential for optimum independence in daily activities of children with CP, orthotic devices such as ankle-foot and knee-ankle-foot orthoses are mostly used for the purpose of correcting or aligning the joints rather than ambulation in this population [38]. Additionally, the parents' responses to the question of their child's mobility distance show that, as the functional level deteriorates, the distances they can move independently become limited to inside and/or around the home, with a moderate correlation between them. These results show that the child's mobility relates to their functional status rather than the usage of an orthotic device.

Regarding the physical conditions of the school, parents of children with lower levels of functionality stated that the physical conditions of the school did not allow their children to have adequate mobility and the children experienced physical difficulties at school, even if their child went to a private school where the conditions are expected to be better due to its economic capabilities.

An examination of the time the Turkish CP population spent in school showed that the children at GMFCS levels I and II mostly spent half of their day at school, while children at GMFCS levels III–V spent less than 4 h at school; suggesting that the time spent in school decreases as the child's motor functions deteriorate. Additionally, most of the children with lower levels of function were fully dependent on another person in school toilet which may be a factor that affects the time spent in school. However, a weak to moderate association was detected between the functional ability of the child and the time spent in school as well as the level of support needed for toileting in this study. Perhaps the most striking finding is that most children, regardless of their functional level, did not attend school full time. Factors other than the functional status of the child were thought to affect the time spent in school such as the type of the education system in Turkey for children in elementary schools. However, since this topic was outside of the aim of the current study, this study did not investigate these factors.

Families, especially parents of children with chronic health conditions, are known to experience many psychological stress, anxiety, and depression from the onset and during the course of the disease. The PSS measures parents' satisfaction with their parenting role based on the influence of the child [30, 31, 39, 40]. In the examination of study population, parents were found to experience a moderate stress level (42 out of 90 points), and the functional status of the children seemed less likely to be a cause of stress for the parents. Although an association exists between parental stress and the child's GMFCS level, and the child's mobility distance according to the parent, the strength of the associations were poor, which suggests that factors other than the child's functional status contribute to the parents' stress levels. Parental stress has been previously described to result from several stressors including the child's behavior problems, emotional status, physical impairments, intensive caregiving demands, and long-term dependence and difficulties in adapting to different environments [39, 40]. The parents also face difficulties with the acceptability of their child in the community and with factors that originate from the parents directly, thus putting the functional level of their child more in the background.

The limited number of participants and obtaining the data of a CP cohort of a single city in Turkey may be considered as limitations of current study. Further studies are needed to involve more participants in order to make more detailed descriptions and global predictions about school-aged Turkish CP population.

Conclusions

This cross-sectional study defines a school-aged Turkish CP population in terms of their functional abilities and the difficulties they experience in a school environment. Despite their different levels of needs for assistance for mobility in community and the different extents of limitations to their mobility and physical difficulties related to school, the motor functions and independence levels of the children did not hinder them to participate school environment. The mobility, independence, functional status, and participation levels of the children were found to relate highly to each other, thus echoing the findings of recent studies performed with CP populations in different countries. The functional classification and mobility distance of school-aged Turkish children with CP has a low impact on parents' stress levels, thus supporting the literature indicating a wide range of factors that affect the parental stress of children with various disabilities.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee (Bezmialem Vakıf University, Clinical Researches Ethical Committee, protocol number 10788) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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