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# GAIT- AND BALANCE-RELATED FACTORS AFFECTING PARTICIPATION IN SCHOOL-AGED CHILDREN WITH UNILATERAL CEREBRAL PALSY TEK TARAFLI SEREBRAL PALSILİ OKUL ÇAĞINDAKİ ÇOCUKLARDA KATILIMI ETKİLEYEN YÜRÜYÜŞ VE DENGE İLE İLGİLİ FAKTÖRLER

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## ABSTRACT

Although gait and balance impairments are prevalent in children with unilateral cerebral palsy (UCP), their effects on participation are not completely elucidated. This study aims to explore factors affecting participation in children with UCP, particularly those related to gait and balance. This descriptive relation-seeker study was completed with 40 children with UCP at Gross Motor Function Classification System (GMFCS) levels I and II (50% female; median age = 11 (7-12)years). "The Gross Motor Function Measure (GMFM-66)", "The Pediatric Balance Scale (PBS)", "The Timed Up and Go test (TUG) and The Functional Mobility Scale (FMS)", and "The BTS G-Walk Spatiotemporal Gait Analysis System" were used to evaluate the gross motor function, balance, functional mobility, and quantitative gait parameters, respectively. "The Canadian Occupational Performance Measure (COPM)" was employed to evaluate participation. Variables affecting the COPM scores were analyzed by multivariate regression analysis. The factors affecting the COPM-performance score were cadence (B =79.859, p = 0.001) and FMS (B = 0.352, p<0.001). These variables explained about 45% of the variation in the COPM-performance score ( $R^2adj = 0.445$ ). The factors affecting the COPM-satisfaction score were cadence (B = 0.188, p=0.044) and stride length of the more affected side (B = 0.137, p=0.008), which explained 26% of the variation in the COPM-satisfaction score (R<sup>2</sup>adj =0 .260).The factors affecting participation in children with UCP were cadence, stride length of the more affected side, and functional mobility. We recommend that rehabilitation specialists consider these factors, as they may be beneficial in designing rehabilitation interventions that effectively promote participation in children with UCP.

**Keywords:** Activities of daily living, balance, cerebral palsy, gait, participation

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168

#### ÖZ

Tek taraflı serebral palsili (UCP) çocuklarda yürüme ve denge bozuklukları yaygın olmasına rağmen, bunların katılım üzerindeki etkileri tam olarak aydınlatılamamıştır. Bu çalışma, okul çağındaki UCP'li çocuklarda katılımı etkileyen özellikle yürüyüş ve denge ile ilgili faktörleri araştırmayı amaçlamaktadır. Bu tanımlayıcı ilişki arayıcı calışma, Kaba Motor Fonksiyon Sınıflandırma Sistemi (GMFCS) seviye I ve II'deki 40 UCP'li çocukla tamamlandı(%50 kız; ortanca yaş = 11 (7-12) yıl). "Kaba Motor Fonksiyon Ölçümü (GMFM-66)", "Pediatrik Denge Ölçeği (PBS)", "Zamanlanmış Kalk ve Yürü Testi (TUG) ve Fonksiyonel Mobilite Skalası (FMS)" ve "BTS G-Walk Spatio-Temporal Yürüyüş Analiz Sistemi" sırasıyla kaba motor fonksiyon, denge, fonksiyonel mobilite ve yürüyüş parametrelerini değerlendirmek icin kullanıldı. Katılımı değerlendirmek için "Kanada Mesleki Performans Ölçümü (COPM)" kullanıldı. COPM puanlarını etkileyen değişkenler çok değişkenli regresyon analizi ile incelendi.COPM-performans puanını etkileyen faktörler kadans (B=79.859, p=0.001) ve FMS (B=0.352, p<0.001) idi. Bu değişkenler COPM-performans puanındaki değişimin yaklaşık %45'ini açıkladı (R<sup>2</sup>adj=0.445). COPMmemnuniyet puanını etkileyen faktörler ise kadans (B=0.188, p=0.044) ve daha fazla etkilenen tarafın adım uzunluğu (B=0.137, p=0.008) idi; bu değişkenler ise COPM-memnuniyet puanının da ki değişimin %26'sını açıkladı (R<sup>2</sup>adj=0.260). UCP'li çocuklarda katılımı etkileven faktörler kadans, daha fazla etkilenen tarafın adım uzunluğu ve fonksiyonel mobilite idi. UCP'li çocukların katılımını etkili bir şekilde destekleyen rehabilitasyon müdahalelerinin tasarlanmasında yararlı olabileceği için rehabilitasyon uzmanlarının bu faktörleri dikkate almalarını öneriyoruz.

Anahtar kelimeler: Günlük yaşam aktiviteleri, denge, serebral palsi, yürüyüş, katılım

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# INTRODUCTION

Affecting 2.11 in every 1000 children in high-income countries, cerebral palsy (CP) is a neuro developmental disorder resulting from non-progressive immature brain impairments and is widely recognized as the most prominent motor disability in children.1-2 Unilateral CP (UCP), the most prevalent type of CP, often arises from hemi-brain atrophy, periventricular lesions, middle cerebral artery infarction, and brain malformations that disrupt the integrity of motor areas. The resulting motor disorders are largely lateralized to one side affecting both upper and lower extremity function.<sup>3</sup> The disorders in body structure and function (such as muscle weakness, spasticity, and reduced selective voluntary control) encountered in UCP may lead to gait and balance impairments.4-5 Although most children with UCP can walk without assistance, gait and balance impairments can affect activities of daily living, engagement in sports and leisure time activities, quality of life, and social interactions in this population.6-7 Compared to their typically developing peers, children with CP experience physical and social difficulties that occur in different ways throughout their lives, and therefore their participation is more restricted.8

Participation is a relatively new concept in rehabilitation science terminology and is defined in the scope of the International Classification of Functioning, Disability, and Health (ICF) framework provided by the World Health Organization.9 According to ICF, participation is described as involvement in life situations and daily activities.<sup>10</sup> Promoting the participation in children with CP is accepted as the ultimate goal of rehabilitation specialists.<sup>11</sup> Thus, understanding the negative or positive contributing factors can help to design rehabilitation interventions that effectively promote participation in children with CP. It was noted that age, gender, motor functions, interests and preferences, physical and social structure of the environment, parental attitude, socioeconomic status, and education level were associated with the participation of children with CP.10 However, to our knowledge, no study deals with the effect of balance and gait parameters on participation in children with UCP. Given that gait and balance impairments are prevalent in children with UCP, it may be valuable to explore the effects of these impairments on participation for guiding the rehabilitation process. Hence, the aim of this study is to explore the factors affecting participation in children with UCP, particularly those associated with gait and balance.

# **Study questions**

1. What are the gait-related factors affecting participation in school-aged children with UCP?

2. What are the balance-related factors affecting participation in school-aged children with UCP?

3. Are gross motor function and functional mobility factors affecting participation in school-age children with UCP?

## MATERIALS AND METHODS

This descriptive relation-seeker study was conducted in the Department of Physiotherapy and Rehabilitation, Faculty of Health Sciences, Lokman Hekim University. The study protocol was accepted by the Lokman Hekim University Scientific Research Ethics Committee. All children and their parents were informed about the study, and an informed consent form was signed.All procedures of the study were carried out in accordance with the Declaration of Helsinki.

#### Participants

A convenience clinical sample of children with CP and their parents who were admitted to the Department of Physiotherapy and Rehabilitation, Faculty of Health Sciences, Lokman Hekim University in Ankara, Türkiye was prospectively included. The Inclusion criteria were (i) having been confirmed with UCP by a pediatric neurologist, (ii) being aged 6 to 12 years, (iii) having Gross Motor Function Classification System (GMFCS) level was I-II, and (iv) having no cooperation problems that may prevent communication. The exclusion criteria were (i) having any previous musculoskeletal surgeries at the lower extremities and (ii) having any pharmacological activity or injection that would inhibit spasticity in the last 6 months. The current study was completed with a total of 40 children with UCP. Sample size and post-hoc power analysis were performed with G\*Power (version 3.1.9 Universität Düsseldorf, Düsseldorf, Germany).12 Since there is no similar study, the effect size of the multiple linear regression, which will investigate the effect of independent variables on COPM-performance and COPM-satisfaction scores, was aimed to be large. Based on the effect size  $|f^2| = 0.35$ , number of predictors = 2,  $\alpha$ = 0.05, and power  $(1-\beta)$  = 0.90, the sample size was calculated as 40. The post-hoc power analysis was performed after the study, and it was found to be 99.9% and 90.7% for the regression models with a statistical significance of  $\alpha$  = 0.05, R<sup>2</sup>adj = 0.445 and 0.260, number of predictors = 2, and sample size = 40.

## **Data Collection Tools**

Face-to-face interviews were conducted to obtain research data between June 2023 and September 2023. "The Gross Motor Function Measure (GMFM-66)", "The Pediatric Balance Scale (PBS)", "The Timed Up and Go test (TUG) and The Functional Mobility Scale (FMS)" and "The BTS G-Walk Spatiotemporal Gait Analysis System" were employed to evaluate the gross motor function, balance, functional mobility, and quantitative gait parameters, respectively. "The Canadian Occupational Performance Measure (COPM)" was employed to evaluate participation.

GMFM-66 was used to evaluate the gross motor functions of children with UCP. It is a valid, reliable, and sensitive instrument performed in children with CP to evaluate five dimensions of gross motor function: (A) lying and rolling, (B) sitting, (C) crawling and kneeling, (D) standing, and (E) walking, running and jumping. In this study, only the D and E dimensions were used in accordance with the functional level of children with UCP at GMFCS I and II levels.<sup>13</sup>

PBS was employed to evaluate the balance of children with UCP. It, which is frequently used as a valid and reliable scale in children with CP, contains items for the static and anticipatory balance. It involves 14 items, and each item is scored between 0 and 4; the highest possible score is  $56.^{14}$  Erden et al. translated the scale into Turkish and demonstrated its validity (concurrent validity: r = 0.692 and p < 0.001) and reliability (ICC for interobserver agreement = 0.915; ICC for intraobserver

The Participation In Children With Unilateral Cerebral Palsy...

agreement = 0.927; Cronbach's alpha = 0.857) in evaluating balance in children.<sup>15</sup>

TUG and FMS were used to evaluate the functional mobility of children with UCP. The TUG is a valid and reliable test that measures distinct features including gait velocity, functional mobility, postural control, and balance. It was repeated three times, and these three values were averaged in the analysis.<sup>16</sup> The FMS is a valid and reliable tool for evaluating functional mobility in children with CP, regarding the use of assistive devices at 3 different distances (500 meters-community, 50 meters-school, and 5 meters-indoor). FMS scores of children with UCP were recorded by asking their parents.<sup>17</sup>

BTS G-Walk Spatio-Temporal Gait Analysis System was employed for evaluating the gait parameters of children with UCP. In this system, the data collected by the sensor fixed at the child's L5-S1 level is transferred to a computer via Bluetooth signals. It, which enables gait analysis by collecting 3D kinematic data, provides for a comparison of the right and left lower extremities. The children with UCP were instructed to walk three times in a 10-meter indoor area, and the average of the three measures was taken into account for statistical analysis.<sup>18</sup>

The participation of children with UCP was evaluated by COPM. It is an individual-centered tool for identifying participation restrictions and prioritizing these restrictions in occupational performance areas.<sup>19</sup> In the adapted version of COPM for children, parents identify their child's 5 most important occupational problems without any intervention by the evaluator and score their child's performance and satisfaction with that performance for each problem on a scale of 0-10. Higher scores demonstrate higher performance and satisfaction.<sup>20</sup>

## **Statistical Analysis**

All statistical analysis was conducted using the IBM SPSS Statistics for Windows v26.0 (SPSS Inc., Chicago, USA). The normal distribution of continuous variables was assessed with visual (histograms and probability graphics) and analytic methods (Kolmogorov-Smirnov and Shapiro-Wilk tests), and all variables except age and BMI were found to be normally distributed. The association between dichotomous variables and continuous variables was examined with the "Point-Biserial Correlation Coefficient", and the association between continuous variables was examined with the "Spearman or Pearson Correlation Coefficient", as appropriate.21 Correlation coefficients between 0.05-0.30 indicated a low correlation, 0.30-0.40 indicated a low-to-moderate correlation, 0.40-0.60 indicated a moderate correlation, 0.60-0.70 indicated a good correlation, 0.70-0.75 indicated a strong correlation and 0.75-1.00 indicated an excellent correlation.<sup>22</sup> "Multiple Linear Regression Analysis" was performed to identify the factors affecting COPM-performance and COPM-satisfaction scores using the possible variables determined in previous analyses. Before the analysis, it was justified that the assumptions (independence of observations, linear relationship between independent variables and dependent variable, homosced asticity, normally distributed residuals) were met. The factors showing a significant correlation with the COPM-performance and COPM-satisfaction scores with a coefficient above 0.30 were examined in terms of multicollinearity, and only one clinically significant parameter showing multicollinearity (correlation coefficient >0.80) was included in the models. The models' fit was evaluated with appropriate goodness-of-fit and residual statistics (adjusted R<sup>2</sup>, residuals vs. fitted plot, and Q-Q plot, residuals vs. predictor plot). A p-value less than 0.05 was determined as an indicator of statistical significance.<sup>21</sup>

#### RESULTS

The study comprised 40 children with UCP with a median age of 11 (7-12) years, of whom 20 (50%) were female. The mean scores for the PBBS, GMFM-66/ D,GMFM-66/E, COPM-performance, and COPMsatisfaction were 48.48±5.04, 48.37±6.37, 12.02±2.18, 22.4±8.84, and 23.15±10.42, respectively. Additional details about the sociodemographic and clinical characteristics of the children are provided in Table 1.

Gender, more affected side, and GMFCS level were not significantly associated with COPM-performance and COPM-satisfaction scores(p>0.05).COPM-performance score had low-to-moderate associations with FMS (r=0.331, p<0.001) and pelvic tilt symmetry (r=0.363, p=0.037), as well as moderate associations with cadence (r=0.578, p<0.001), gait cycle duration (LAS) (r=-0.608, p<0.001), and gait cycle duration (MAS) (r=-0.417, p=0.007). However, there was no association of COPM-performances core with PBBS, TUG, GMFM-66/D, GMFM-66/E, and other gait parameters (p> 0.05) (Table 2).

COPM-satisfaction score had low-to-moderate associations with cadence (r=0.382, p=0.015),gait cycle duration (LAS) (r=-0.339, p=0.033), and stride length (LAS) (r=0.348, p=0.028), as well as moderate association with stride length (MAS) (r=0.464, p=0.003). However, there was no association of COPM-satisfaction score with PBBS, TUG,FMS, GMFM-66/D, GMFM-66/E, and other gait parameters (p>0.05) (Table 2).

At least one of the independent variables in the regression models was found to be a significant predictor (factor) and the models were generally significant (COPM-performance: F(2.39)=16.647 and p<0.001, COPM-satisfaction: F(2.39)=7.846 and p=0.001). The cadence (B=0,327, p<0.001) and FMS(B=6,599, p=0.003) had significant positive effects on the COPM-performance score (model 1). They accounted for about 45% of the variance in the COPM-performance score ( $R^2_{adj}=0.445$ ). The cadence (B=0.188, p=0.044) and stride length (LAS)(B=0.137, p=0.008) had significant positive effects on the COPM-satisfaction score (model 2). They accounted for 26% of the variance in the COPM -satisfaction score( $R^2_{adj}=0.260$ )(Table 3).

#### DISCUSSION

In the current study, we studied the gait- and balancerelated factors affecting participation in children with UCP. The findings revealed that cadence and functional mobility were significant factors affecting participation performance, while cadence and stride length of the more affected side were significant factors affecting participation satisfaction.

To our knowledge, there exists no study dealing with the effect of gait parameters on participation. Thus, the

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**Table 1.** The sociodemographic and clinical characteristics of the children with UCP (n=40)

Age (years)	11(7-12)
BMI (kg/m²)	19.11 (17.33-21.33)
PBBS	48.48±5.04
TUG	7.49±2.14
FMS	5.43±0.5
GMFM-66/D (standing)	48.37±6.37
GMFM-66/E (walking, running, jumping)	$12.02 \pm 2.18$
Gait Parameters	
Cadence (step/min)	113.92±16.35
Gait Velocity (m/s)	$1.18\pm0.26$
Gait Cycle Duration (s)	
LAS	1 11+0 19
MAS	1 12+0 17
Stride Length (Min)	1.12±0.17
I AS	1 10+0 22
MAS	1.19±0.23
MAS Stride Length $(0/)$	1.2±0.22
Stride Lengit (%)	0( 37 . 33 0
LAS	96.37±32.8
MAS	99.04±30.35
Step Lenght (%)	
LAS	48.57±3.51
MAS	50.99±3.64
Stance Phase (%)	
LAS	61.69±3.07
MAS	59.5±3.91
Swing Phase (%)	
LAS	38.46±3.22
MAS	50.14±64.14
First Double Support Phase (%)	
LAS	10.89±2.21
MAS	$10.43 \pm 2.47$
Single Support Phase (%)	
LAS	39.74±3.71
MAS	38.15±3.01
Gait Symmetry	83±11.67
Pelvic Tilt Symmetry	33.59±26.71
Pelvic Obliquity Symmetry	84.13±16.24
Pelvic Rotation Symmetry	87.79±16.85
COPM-performance	22.4±8.84
COPM-satisfaction	23,15+10,42
	n (%)
Gender	
Female	20 (50)
Male	20 (50)
More Affected Side	20 (00)
Right	24 (60)
I off	16 (40)
CMFCS Lovals	10 (40)
	10 ( <i>AE</i> )
	18 (45)
Level II	22 (55)

Values are given as X±SD or median (25th/75th centile). X, mean; SD, Standard Deviation; BMI, Body Mass Index; GMFCS, Gross Motor Function Classification System; PBBS, Pediatric Berg Balance Scale; TUG, Timed Up and Go Test; FMS, Functional Mobility Scale; GMFM-66, Gross Motor Function Scale Measure; COPM, Canadian Occupational Performance Measure; LAS, Less Affected Side; MAS, More Affected Side.

current study is the first to show that cadence and stride length of the more affected side affect participation in children with CP. Bourgeois et al. reported children with CP had reduced spatiotemporal gait parameters including cadence and stride length, which may seriously predispose them toward falls.<sup>23</sup> These findings imply that cadence and stride length may affect participation by causing the child with CP to fall during activities of daily living. The current study showed that gait parameters affect not only participation performance but also participation satisfaction. This finding, which reveals the perception of children with CP towards their daily living, has clinical significance for rehabilitation specialists. Thus, we suggest that improving the cadence and stride length of the more affected side is a key clinical goal in the rehabilitation of children with UCP where the ultimate aim is to promote participation. On the other hand, the absence of an effect of gait parameters on participation, with the exception of cadence and stride length, may be attribut-

The Participation In Children With Unilateral Cerebral Palsy...

<b>Table 2.</b> Associations of the COPM scores with other variable	able 2. Associations of the COPM s	scores with other variab	les
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			COPM-performance	<b>COPM-satisfaction</b>
Condon		r	0.132	-0.117
Genuer		р	0.418	0.474
More Affected Side		r	0.068	0.062
		р	0.678	0.702
GMFCS Level		r	-0.154	0.272
		р	0.342	0.089
PBBS		r	0.306	0.123
		р	0.055	0.449
Gait Parameters				
Cadanaa		r	0.578	0.382
Cadence		р	<0.001*	0.015*
Gait Cycle Duration	LAS	r	-0.608	-0.339
	LAS	р	<0.001*	0.033*
	MAS	r	-0.417	-0.277
	MAS	р	0.007*	0.083
Stride Lenght (%)	LAS	r	0.037	0.348
	LAS	р	0.823	0.028*
	MAS	r	0.127	0.464
	MAS	р	0.434	0.003*
Pelvic Tilt Symmetry		r	0.363	-0.052
		р	0.021*	0.752
TUG		r	0.301	0.121
		р	0.059	0.459
FMS		r	0.331	-0.096
		р	0.037*	0.555
GMFM-66/D		r	0.154	0.126
		р	0.342	0.438
GMFM-66/E		r	0.193	-0.031
		р	0.234	0.851

\*p<0.05; r, correlation coefficient; Gross Motor Function Classification System; PBBS, Pediatric Berg Balance Scale; TUG, Timed Up and Go Test ; FMS, Functional Moility Scale; GMFM-66, Gross Motor Function Scale Measure; COPM, Canadian Occupational Performance Measure; LAS, Less Affected Side; MAS, More Affected Side.

Table 3 Mu	ltinle linear	regression and	alveis results	of the factors	s affecting COPM	I scores
Table 5. Mu	iupie inieai	i egi ession ana	ilysis results	of the factors	s affecting COFM	1 Scores

	В	95% CI	t	р	VIF
Model 1					
Constant	-50.641	-79.173/-22.109	-3.596	0.001*	-
FMS	6.599	2.322/10.877	3.126	0.003*	1.005
Cadence	0.327	0.196/ 0.458	5.057	<0.001*	1.005
Model 2					
Constant	-11.820	-32.932/9.293	-1.134	0.264	-
Cadence	0.188	0.005/0.370	2.086	0.044*	1.05
Stride Lenght of MAS	0.137	0.039/0.235	2.828	0.008*	1.05

\*p<0.05; B, Un standardized coefficient; CI, Confidence Interval; VIF, Variance Inflation Factor; MAS, More Affected Side; COPM, Canadian Occupational Performance Measure.

Model 1: The dependent variable is COPM-performance, n=40, R<sup>2</sup><sub>adj</sub>=0.445, Model: Backward Method.

Model 2: The dependent variable is COPM-satisfaction, n=40, R<sup>2</sup><sub>adj</sub>=0.260, Model: Backward Method.

able to the fact that our study population included GMFCS level I-II children with out severe gait disorders. The present study revealed that functional mobility affects participation in school-age children with UCP. Furtoda et al. stated that functional mobility had a strong association with the school participation of children and youths with CP.<sup>24</sup> Schenker et al. noted that children with CP at GMFCS I and II levels had higher participation in regular school classes or special classes compared to children at GMFCS levels III.<sup>25</sup>Since they

learn new tasks, establish friend ships, develop social roles, and their social environments rapidly broaden during the school-age period, school is one of the most essential participation areas for children with CP. There fore, rehabilitation approaches that focus on increasing functional mobility and environmental adjustments to address mobility barriers both with in and outside of the school may promote participation in children with UCP.

In this study, gender and age did not have a significant

effect on participation in school-age children with UCP. Similar to our study, Seyhan-Bıyık et al. reported that gender is not effective in participation in children with CP.<sup>26</sup> In contrast to our study, Reedman et al. stated that there is a significant association between age and participation in children with CP at the GMFCS I-III levels and participation score decreases as age increases. They speculated that decreased levels of physical activity and parental control, as well as children's preference for sedentary leisure time activities as age increases, may be responsible for this association.<sup>27</sup> The possible reasons for why there was no significant association between age and participation in our study are that children with CP at the GMFCS I-II levels have fewer participation restrictions and better ambulatory levels than children with CP at the GMFCS III level.<sup>28</sup> From this viewpoint, it can be inferred that children with CP at the GMFCS I-II levels could maintain their participation despite their increasing age.

This study demonstrated that balance and gross motor function have no significant effect on participation in school-age children with UCP. The PBS is used to assess balance, and scores between 41 and 56 are interpreted as good balance.29 We consider that balance is not a significant factor in participation because the children with CP at the GMFCS I-II levels in our study have good balance, with an average PBBS score of 48. Vila-Nova et al. stated that compared to peers without motor disorders, children with CP at GMFCS II-V participate in team sports, individual physical activities, and cycling less frequently. However, they reported no differences between children with CP in GMFCS I and peers without motor impairments in terms of physical activity participation.30 This finding implies that gross motor function is associated with physical activity participation only in children with CP at higher levels of GMFCS. Furthermore, it was noted that children with CP at the GMFCS I-II level are less restricted in their physical activity participation compared to children with CP at other GMFCS levels.<sup>27</sup> Considering that our study sample consisted of children with UCP at GMFCS I -II level, we infer that children with CP at lower levels of GMFCS have a mild motor impairment and that this motor impairment does not prevent participation.

The present study had several limitations. First, the convenience sampling method was used to include children from Ankara province. Second, our study sample consisted of school-age children with UCP at the GMFCS I-II level. These two limitations may weaken the generalizability of the findings and the representativeness of the sample. Future studies should use random sampling methods and include participants in other CP types, age groups, and GMFCS levels. Third, only cross-sectional associations and effects could be examined due to the design of our study. Nevertheless, our study may provide preliminary data and shed light on further longitudinal or experimental studies.

#### CONCLUSION

This study shows that the factors affecting participation in children with UCP were cadence, stride length of the most affected side, and functional mobility. We believe that awareness of the effect of these factors on participation may be crucial in guiding participationoriented rehabilitation interventions.

**Ethics Committee Approval:** This study was approved by the Ethics Committee of Lokman Hekim University (June 13, 2023, Number: 2023/087).

**Informed Consent:** Written and/or verbal consent was obtained from children and their parents participating in the study.

**Peer-review:** Externally peer-reviewed.

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