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ORIGINAL ARTICLE

Parkinson hastalarında Pilates egzersizlerinin core kas kalınlığı, fiziksel performans ve yorgunluk üzerine etkisi: Randomize kontrollü bir çalışma

Effect of Pilates exercises on core muscle thickness, physical performance, and fatigue in patients with Parkinson's disease: A randomized controlled trial

Derya ÇAĞLAR[1], Arzu GÜÇLÜ-GÜNDÜZ[2], Ahmet TÜFEKÇİ[3], Mehmet BEYAZAL[4], Mustafa-Umut ÇAĞLAR[5], Sefa ELDEMİR[6]

Öz

Amaç: Parkinson hastalığı (PH) olan hastalarda Pilates egzersizlerinin core kas kalınlığı, fiziksel performans, yorgunluk, günlük yaşam aktivitesi (GYA) ve yaşam kalitesi (YK) üzerindeki etkilerinin incelenmesi amaçlandı.
Yöntem: Bu çalışma, Pilates veya kontrol grubuna rastgele atanan 34 hasta (her biri n=17) ile gerçekleştirildi. Pilates grubuna 8 hafta boyunca haftada 3 gün Pilates eğitimi verilirken, kontrol grubuna ev programı olarak solunum egzersizleri, aktif eklem hareket açıklığı egzersizleri ve gevşeme egzersizleri verildi. Core kas kalınlığı ultrasonografi ile, core stabilitesi, core kuvvet ve dayanıklılık testleri ile değerlendirildi. Alt ekstremite fonksiyonel kuvveti 5 Kez Otur-Kalk Testi ile, denge Berg Denge Skalası ile, fonksiyonel mobilite Zamanlı Kalk ve Yürü Testi ile, fonksiyonel egzersiz kapasitesi ise 6 Dakika Yürüme Testi ile değerlendirildi. Yorgunluk, Parkinson Yorgunluk Ölçeği-16 ile değerlendirildi.
Bulgular: Pilates grubunda transversus abdominus ve multifidus kas kalınlıkları (sağ taraf multifidus kası hariç), fiziksel performans parametreleri, yorgunluk, GYA ve YK'de gelişme görüldü ($p<0,05$). Kontrol grubunda ise sadece GYA'da iyileşme görüldü ($p<0,05$).
Sonuç: Sonuçlar, PH'li bireylerde Pilates sonrası core kas kalınlığının yanı sıra fiziksel performans, yorgunluk, GYA ve YK'de iyileşme olduğunu göstermektedir. Sonuç olarak, core bölge antrenmanı olan Pilates, core bölge kaslarını eğitmek ve fonksiyonel sonuçları, yorgunluğu ve günlük aktiviteleri iyileştirmek için kullanılabilir.
Anahtar kelimeler: Parkinson hastalığı, Pilates egzersizleri, Abdominal kaslar, Fiziksel performans, Core stabilite.

Abstract

***Purpose**: It was aimed to examine the effects of Pilates exercises on core muscle thickness, physical performance, fatigue, activities of daily living (ADL), and quality of life (QoL) in patients with Parkinson's disease (PwPD).*
***Methods:** This study was conducted with 34 patients randomly assigned to the Pilates or Control group (n=17 each). The Pilates group received Pilates training 3 days a week for 8 weeks, while the control group received breathing exercises, active range of motion exercises, and relaxation exercises as a home program. Core muscle thickness was evaluated by ultrasonography and core stability was evaluated by core strength and endurance tests. Lower extremity functional strength was evaluated with the 5 Times Sit-Up Test, balance with the Berg Balance Scale, functional mobility with the Timed Up and Go Test, and functional exercise capacity with the 6-Minute Walk Test. Fatigue was evaluated with the Parkinson's Fatigue Scale-16,.*
***Results:** Transversus abdominus and multifidus muscle thicknesses (except for right side multifidus muscle), physical performance parameters, fatigue, ADL, and QoL improved in the Pilates group ($p<0.05$). In the control group, improvement was observed only in ADL ($p<0.05$).*
***Conclusion:** Results show core muscle thickness as well as improved physical performance, fatigue, ADL, and QoL after Pilates in PwPD. As a result, core-based training, Pilates, may be used to train core muscles and improve functional results, fatigue, and daily activities.*
***Keywords:** Parkinson's disease, Pilates exercises, Abdominal muscles, Physical performance, Core stability.*

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INTRODUCTION

Parkinson's disease (PD) is a progressive neurodegenerative disorder characterized by both motor and non-motor symptoms.[1] Patients experience increased difficulties in mobility as a result of decreased movement skills, balance, muscle strength, postural alignment, and aerobic capacity. All of these lead to a decrease in independent activities of daily living, resulting in a decrease in quality of life.[2] In the management of the disease, together with medical treatments, exercise has an important place.[3]

Exercise provides effective use of dopamine by regulating dopamine circulation in PD.[4] It has been shown to contribute to neuroprotection, neurorestorative, and neuroplasticity and, as a result, slows the progression of PD.[5] Exercise has been shown to effectively improve motor impairments such as muscle strength, balance, mobility, aerobic capacity, walking, and freezing and, non-motor impairments such as cognitive function and sleep quality in PD.[6] Traditional exercises consist of interventions to improve the symptoms of patients with PD (PwPD), such as breathing, relaxation exercises, active range of motion, stretching, strengthening, and balance training.[7-9] Nowadays, while traditional exercise methods are still used, it is seen that the exercise habits of the patients have changed, They prefer sports that they can enjoy individually or in groups such as music and dance therapy, Pilates, yoga, and Tai Chi, and there are participating more in these training compared to classical neurorehabilitation training.[7,10,11] Pilates, one of the most remarkable exercise methods, was developed at the beginning of the 20th century by Joseph Pilates as a core-based mind-body exercise method that improves body smoothness and awareness.[12] The effects of Pilates on lower extremity muscle strength,[13] balance,[13-15] mobility,[14-16] motor impairments,[13,15] and quality of life[17] have been examined in PD. Although it is stated in these studies that Pilates can be used as an exercise method in PD, it is said that further studies are needed. Additionally, although Pilates is a core stability-based training method, its effects on core stability and the core muscle thickness have not been investigated yet in PD. Demonstrating these effects may be instructive in order to better understand the effects of Pilates on functional improvements in PD.

Therefore, the purpose of this study is to investigate the effects of Pilates on the core muscle thickness, core stability, lower extremity muscle strength, balance, functional mobility, functional exercise capacity, fatigue activities of daily living (ADL), and quality of life (QoL).

METHODS

Subjects

Thirty-four patients (26 men and 8 women; mean age 61.41±11.82 years) with idiopathic PD participated in this study. Inclusion criteria were: (a) 40-80 years of age and (b) Hoehn and Yahr stages 1 through 2.5. Exclusion criteria were: (a) the presence of cardiovascular, pulmonary, orthopedic, or history of different neurological diseases other than PD that limited participation in Pilates and (b) a Standardized Mini-Mental Test score <24. There was no change in medication type or dose in any patient throughout the study. This study was in accordance with the Declaration of Helsinki and written informed consent was obtained from all participants.

The study was approved by the Republic of Gazi University Faculty of Medicine Clinical Research Ethics Committee (issue: 2019/10 date: 10.09.2019).

Procedure

Participants were assigned to the Pilates group and control group with computer-generated random numbers using the simple randomization method. Simple randomization is a method that ensures that the assignment of subjects to a particular group is random and is reliable in creating similar numbers of subjects in groups.[18] While the Pilates group performed only Pilates exercises, the control group followed with a home program. Pilates training was given by a physiotherapist (DC) who is certified by the Australian Institute of Pilates and Physiotherapy (APPI) and working on Pilates and neurological physiotherapy. Evaluations were made before and after treatment by a blinded physiotherapist (MUC).

Interventions

Pilates was carried out as group exercises for 8 weeks, 3 days a week. Before starting the

exercise training, all subjects were taught the key elements of Pilates for 1 session. These key elements were breathing, centering, rib cage placement, shoulder girdle placement, and head and neck position. Each movement was shown firstly by the physiotherapist so that the patients could perform the movements correctly. During Pilates, movements were controlled by the physiotherapist and necessary corrections were made with verbal or tactile stimuli.

Pilates started with standing warm-up exercises and centering in the supine position. For centering, the abdominal hollowing - abdominal draw-in maneuver was used to activate the M. transversus abdominis (TrA) muscle.[19] The intensity of the exercises was increased using different positions and elastic bands (Theraband Elastic Band Hygienic Corporation, Akron, Ohio). The details of Pilates are presented in Figure 1.

Figure 1. Pilates training program.

Centring	Warm-up (5 min)
Segmental extremity movements	
Overhead reach	Pilates (50 min)
Abdominal preparation	Clam
Oblique preparation	Hip twist
One leg stretch	Swimming
Scissors	Arm opening
One leg circle	Side bend
Double leg stretch	Breast stroke
Heels together toe apart	Cobra
Hundreds	Spine twist
Leg pulls in prone	Mermaid
Shoulder bridge	Chest lift
	Crisscross
Single knee to chest	Cool-down (5 min)
Double knee to chest	
Camel stretch	
Cat stretch	
Standing quadriceps stretch	
Seated forward bend stretch	
Lying trunk rotation	

The control group was followed up with a home program including breathing, active range of motion, and relaxation exercises. The control group performed the exercises 3 days a week for 8 weeks, as in the Pilates group. Additionally, the control group was followed with an exercise chart, and they were called by phone every week to check whether the exercises were performed regularly.

Outcome measures

TrA and Multifidus (MF) muscles were visualized by ultrasonography, and evaluations were performed by an experienced specialist radiologist who was blinded to the case groups. Toshiba Aplio 500 US (Toshiba Medical Systems Corporation, Otawara, Japan) device was used for all ultrasonography examinations. Ultrasound recordings were made by using B-mode ultrasound. The TrA muscle thickness was examined by the 12-Mhz linear transducer placed transversely over the iliac crista in the mid-axillary line while the patient was lying in the supine position. The MF muscle thickness was examined by the 5-Mhz convex transducer while the patient was lying in a prone position with a pillow under the abdomen. Ultrasonographic imaging of the MF muscle was performed in the transverse plane and thickness measurement was taken from the cross-sectional area using the curved probe. All measurements were performed both in the resting position and during the abdominal drawn-in maneuver to minimize the activity of the superficial global muscles and emphasize the deep local muscle activity.[20,21]

Core strength was evaluated with sit-up test and modified push-up test. The sit-up test was started with the knees flexed at 90° on a mat, the feet stabilized and the hands placed behind the head. The patient was asked to the trunk flexion up to the lower angle of the scapula.[22,23] The modified push-up test was performed in the prone position with the arms, elbows, and knees flexed. The subjects were asked to raise the head, shoulders, and trunk off the ground by bringing their elbows to full extension.[24]

Core endurance was evaluated with lateral bridge test, trunk flexor endurance test, and prone bridge test. In the lateral bridge test, the subjects were asked to lie on their right/left side, to raise their body on their forearms and toes, and to maintain their position.[23] In the trunk flexor endurance test, subjects were asked to remain in the 60° trunk flexion position while the hip and knee were in 90° flexion.[23] In the

prone bridge test, the subjects were positioned in the prone position, on their forearms with both arms shoulder-width apart, both feet open to hip-width, elbows flexed to 90°. They were asked to raise their torso by placing their weight on their forearms and toes.[25]

The functional strength of the lower extremity was evaluated with the 5 Times Sit-Up Test (5XSST).[26] Balance was assessed with the Berg Balance Scale (BDS) which is widely used to assess the ability to maintain balance during different positions and postural changes.[27] Functional mobility was evaluated with the Timed Up and Go Test (TUG)[28] and functional exercise capacity was evaluated with the 6-Minute Walk Test (6-MWT).[29]

The Parkinson's Fatigue Scale-16 (PAS-16) was used to examine the effect of fatigue, one of the non-motor findings associated with Parkinson's, on daily life and to evaluate its physical effects.[30] The scale consists of 16 questions rated between 1 (strongly disagree) and 5 (strongly agree). When the total score was 8 points or more, it is considered as fatigue. In this study, the Turkish version of the PAS-16 scale, whose reliability and validity were investigated, was used.[31]

ADL was evaluated with activities of daily living (II) subscale of the Unified Parkinson's Disease Rating Scale (UPDRS).[32] In this study, the Turkish version of the UPDRS scale, whose reliability was investigated, was used.[33] QoL was assessed with the Parkinson's Disease Quality of Life Questionnaire-39 (PDQ-39) in patients with PD.[34] The PDQ-39 has eight dimensions ranging from 0 to 100; being the higher the score, the worse the QoL. In this study, the Turkish version of the PDQ-39 scale, whose reliability and validity were investigated, was used.[35]

Statistical analysis

The sample size was determined by performing a power analysis (G*power version 3.1.9.2, Heinrich Heine Universitaet, Düsseldorf, Germany). For this, a pilot study was conducted and it was carried out considering the clinically significant differences in the core endurance test scores. According to the power analysis results, the average number of individuals for each group was determined as 17 participants (power=95% and alpha=0.05). Statistical analysis of the study was

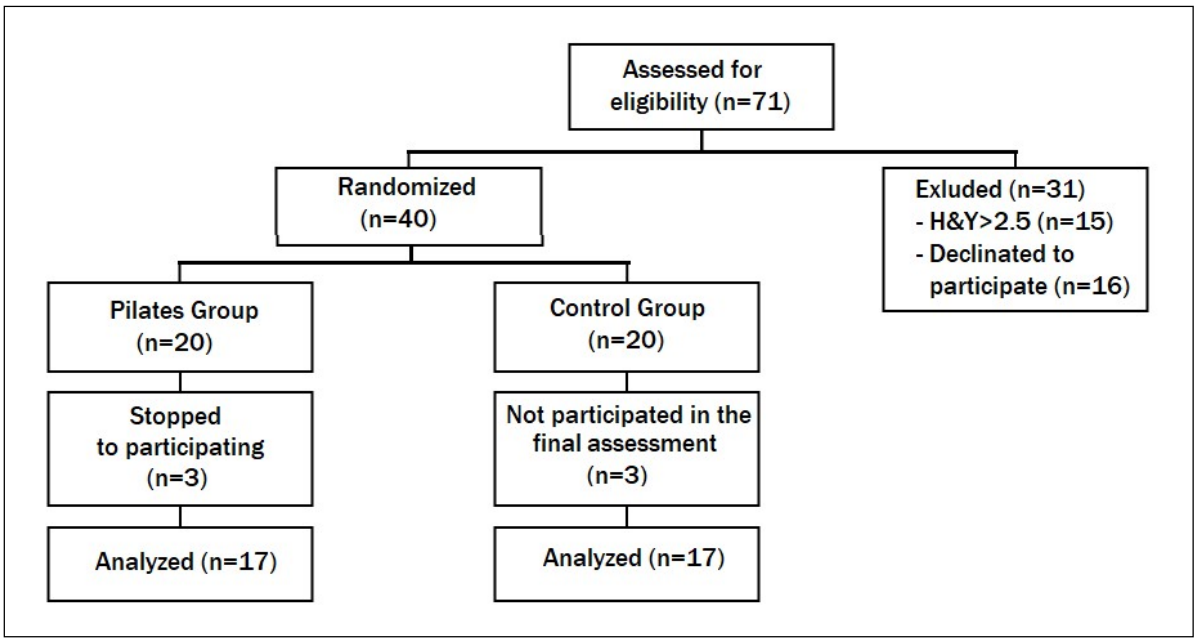

Figure 2. Participants flow through the study. Consolidated Standards of Reporting Trials (CONSORT) flow chart.

performed using the SPSS version 23 (SPSS inc. Chicago, IL, USA) program. The normality and homogeneity of variances were assessed via a Shapiro-Wilk test. Statistics of numerical variables were expressed by giving the mean ± standard deviation for normally distributed variables, and the median and interquartile range (25-75 interquartile range: IQR) for non-normally distributed variables. Descriptive statistics of categorical variables were expressed as frequency and percentage (%). Demographic characteristics and outcome measures of participants were compared between the groups using the independent samples t-test, Mann–Whitney U test, or the Chi-square test. Comparison of data within groups was made by using the dependent group's t-test or Wilcoxon test. The statistical error level was taken as $p<0.05$.

RESULTS

A total of 71 participants were assessed for eligibility, with 34 randomized to the Pilates group or the control group (see Figure 2).
Age, gender, body mass index, disease duration, Hoehn and Yahr stage, and outcome measures (except left side TrA muscle thickness during abdominal drawn-in) were similar between the groups ($p>0.05$) (Table 1).

Table 2 and 3 show the comparison of outcome measures for groups. The core muscle thickness, core stability, lower extremity functional strength, balance, functional mobility, and functional exercise capacity improved in the Pilates group ($p<0.05$). In addition, fatigue decreased and ADL improved in the Pilates group ($p<0.01$). There was no significant increase in right side multifidus muscle thickness only in the Pilates group ($p>0.05$). The quality of life developed in both groups, improved more in the Pilates group than in the control group ($p<0.05$). The PDQ-39 (0-156) change scores were -38.05±15.68 and -3.35±4.35 for Pilates Group and Control Group, respectively. There was a difference between the two groups ($p<0,001$).

DISCUSSION

This study has shown that an 8-week Pilates exercise program resulted in significant improvements in both sides TrA and left multifidus thickness, core stability, lower extremity functional strength, balance, functional mobility functional exercise capacity, fatigue, ADL and QoL in PwPD.

Core muscle strength and endurance improved in the Pilates group after 8 weeks, while it did not change in the control group in this study. The effect of pilates on core muscle strength and endurance in patients with chronic low back pain[36,37] or neurological diseases[10,38,39] has previously been investigated. Only one of these studies reported that Pilates produced significant improvements in core strength and endurance in PwPD.[39] The study stated that improvements in core endurance after 6-week Pilates training in PD were associated with increases in TrA activity which demonstrated this with ultrasound imaging, the main muscle of core stability. In our study, core muscle strength and endurance were evaluated, and the findings were also supported by ultrasonographic examination. An increase in TrA muscle thickness was detected both in the resting position and during the abdominal retraction maneuver. At the end of the study, a similar increase in thickness was observed in the left multifidus muscle. Our results showed the effectiveness of Pilates training on core muscles, consistent with previous studies. The lack of improvement in the control group may be due to the fact that the exercise content is not directly aimed at improving core muscle strength and endurance.
Another important result of this study is that there was an improvement in functional strength of the lower extremity in the Pilates group, only. Pilates is basically a training that aims to improve core stability. Core stability does not mean static stability, it means the ability to dynamically adapt to the movement of the trunk and extremities and maintain balance. In Pilates, core muscles are activated with extremity and trunk movements.[12,40] Additionally, by using resistance bands and moving ground (Pilates ball), this activation is tried to be increased even more. Thus, both core and extremity muscles are strengthened, and balance is improved. In our study, we think that functional strength in the lower extremity increased with this basic mechanism. Another reason for strengthening the lower extremity muscles is that the core area is the key point for

extremity movements. If the core muscles are strong and stable, extremity movements become free, and strength and coordination increase in the extremities.[14] Based on this reason, it can be said that the increase in core stability is an important factor in the development of the functional strength of the lower extremity. Consistent with the present study, Cardalda et al.[13] found that the functional strength of the lower extremity improved in PwPD after Pilates. In addition, we think that improving the sit-to-stand activity, which is one of the most difficult activities for Parkinson's patients in daily life, is one of the important achievements of education as mentioned above.

Another important result of this study in the Pilates group is the improvement in balance. As a result of the nature of the Pilates exercise method, we can easily expect an improvement in balance. In the literature, there are studies examining the effects of Pilates on balance with mild to moderate PH patients, and the result of the present study is consistent with the literature.[13-15] Although these studies attribute

Table 1. Comparison of demographic and baseline characteristics of the groups.

		Pilates Group (N=17)	Control Group (N=17)	p
Age (years) (e)		61.0 (50.0-70.5)	69.0 (63.5- 73.5)	0.068 (b)
Gender (Female/Male) (n (%))		4/13 (24/76)	4/13 (24/76)	1.000 (c)
Body mass index (kg/m^2) (e)		26.22 (24.65-31.24)	30.42 (28.09-33.46)	0.052 (b)
Disease duration (years) (e)		6.00 (1.50-7.00)	3.00 (2.00-4.50)	0.251 (b)
Hoehn and Yahr stage (0-5) (n (%))	1	5 (29)	6 (35)	
	2	11 (65)	10 (59)	0.747 (c)
	2.5	1 (6)	1 (6)	
Core muscle thickness (d)				
M. Transversus abdominus (mm)				
Resting position	Right	3.79±0.81	4.31±0.80	0.143 (a)
	Left	3.74±0.72	4.45±0.83	0.051 (a)
Abdominal drawn-in	Right	4.69±0.83	5.40±1.03	0.092 (a)
	Left	4.71±0.86	5.79±1.22	0.028* (a)
M. Multifidus (mm)				
Resting position	Right	21.97±3.96	21.10±2.04	0.524 (a)
	Left	21.66±3.26	21.59±1.99	0.950 (a)
Abdominal drawn-in	Right	20.90±3.57	20.70±2.13	0.881 (a)
	Left	21.21±3.15	20.85±1.37	0.730 (a)
Core Power (e)				
Sit-up (repetition/30 sec)		3.94 (0.00-7.00)	4.00 (0.00-7.00)	0.902 (b)
MPT (repetition/30 sec)		7.17 (4.00-11.00)	5.76 (0.50-9.00)	0.342 (b)
Core Endurance (e)				
Side bridge Test (sec)	Right	10.41 (0.00-15.50)	6.52 (0.00-12.50)	0.315 (b)
	Left	10.76 (3.50-14.00)	5.23 (0.00-8.50)	0.056 (b)
Trunk Flexor Test (sec)		5.94 (0.00-5.50)	1.64 (0.00-2.50)	0.338 (b)
Prone Bridge (sec)		20.82 (8.50-28.00)	14.17 (3.00-26.00)	0.202 (b)
Five Times Sit to Stand Test (5XSST) (sec) (d)		20.88±7.04	18.47±3.89	0.228 (a)
Berg Balance Scale (BBS) (0-56) (d)		50.41±4.43	51.64±3.49	0.374 (a)
Time Up and Go Test (TUG) (sec) (e)		14.35 (11.00-18.00)	13.29 (11.00-15.00)	0.664 (b)
6-Minute Walk Test (6-MWT) (d)				
Distance (m)		360.00±91.63	378.18±60.65	0.500 (a)
Maximal heart rate reached (%)		58.14±6.10	58.84±3.00	0.221 (a)
PFS-16 (16-80) (d)		51.94±7.13	47.64±8.99	0.193 (a)
UPDRS-II (0-52) (d) (e)		13.35±5.54	11.05 (6.00-14.50)	0.156 (b)
PDQ-39 (0-156) (d)		49.47±17.75	39.41±18.14	0.112 (a)

*p<0.05. (a): Independent Samples t-Test. (b): Mann–Whitney U Test. (c): Chi-Square Test. (d): Mean±SD. (e): Median (IQR). MPT: Modified push-up test. PFS-16: Parkinson's Disease Fatigue Scale. UPDRS-II: Unified Parkinson's Disease Rating Scale-Motor assessment subscale. PDQ-39: Parkinson's Disease Quality of Life Questionnaire-39.

Table 2. A comparison of the previous and subsequent measurements of parameters for the Pilates Group (N=17).

		Before	After	p
Core muscle thickness (d)				
M. Transversus abdominus (mm)				
Resting position	Right	3.79±0.81	4.74 ±0.98	<0.001 (a)
	Left	3.74±0.72	4.80±0.75	<0.001 (a)
Abdominal drawn-in	Right	4.69±0.83	6.45±1.19	<0.001 (a)
	Left	4.71±0.86	6.67±1.23	<0.001 (a)
M. Multifidus (mm)				
Resting position	Right	21.97±3.96	20.74±2.81	0.136 (a)
	Left	21.66±3.26	22.04±3.13	0.015* (a)
Abdominal drawn-in	Right	20.90±3.57	20.49±2.86	0.547 (a)
	Left	21.21±3.15	21.70±2.58	0.044* (a)
Core Power (e)				
Sit-up (repetition/30 sec)		3.94 (0.00-7.00)	11.17 (6.50-16.00)	<0.001 (b)
MPT (repetition/30 sec)		7.17 (4.00-11.00)	17.52 (11.00-21.00)	<0.001 (b)
Core Endurance (e)				
Side bridge Test (sec)	Right	10.41 (0.00-15.50)	37.41 (17.00-50.50)	<0.001 (b)
	Left	10.76 (3.50-14.00)	41.76 (22.50-56.00)	<0.001 (b)
Trunk Flexor Test (sec)		5.94 (0.00-5.50)	16.05 (4.50-24.00)	<0.001 (b)
Prone Bridge (sec)		20.82 (8.50-28.00)	61.00 (44.00-82.50)	<0.001 (b)
Five Times Sit to Stand Test (5XSST) (sec) (d)		20.88±7.04	10.64±2.91	<0.001 (a)
Berg Balance Scale (BBS) (0-56) (d)		50.41±4.43	55.35±0.70	<0.001 (a)
Time Up and Go Test (TUG) (sec) (e)		14.35 (11.00-18.00)	8.47 (7.00-10.00)	<0.001 (b)
6-Minute Walk Test (6-MWT) (d)				
Distance (m)		360.00±91.63	482.82±98.79	<0.001 (a)
Maximal heart rate reached (%)		58.14±6.10	60.52±4.52	0.035* (a)
PFS-16 (16-80) (d)		51.94±7.13	32.11±3.56	<0.001 (a)
UPDRS-II (0-52) (d)		13.35±5.54	3.70±2.91	<0.001 (a)
PDQ-39 (0-156) (d)		49.47±17.75	11.41±6.45	<0.001 (a)

*p<0.05. (a): Independent Samples t-Test. b: Mann–Whitney U Test. (d): Mean±SD. (e): Median (IQR). MPT: Modified push-up test. PFS-16: Parkinson's Disease Fatigue Scale. UPDRS-II: Unified Parkinson's Disease Rating Scale-Motor assessment subscale. PDQ-39: Parkinson's Disease Quality of Life Questionnaire-39.

the development of balance to the improvement in core stability, it is seen that they do not prove this with the improvement in the strength, endurance, and core muscle thickness. This study provides evidence for the hypothesis underlying Pilates' improvement of balance in PD.

Although Pilates is not a gait training, we found that our patients walked faster and their walking distance increased, according to TUG and 6-MWT. Johnson et al.[15] have shown that Pilates is beneficial to PD patients who are prone to falls and reported significant improvements in their step cadence and mobility. Similarly, Pandya et al.[14] and Daneshmandi et al.[16] who investigated the effects of Pilates on PD, found that functional mobility increased in their studies. Both these studies and current study show that walking performance can improve in patients with a core-based training. It can be said that the basis of this development is similar to the underlying reasons for the development achieved in sit to stand.

The 6-MWT evaluates both exercise capacity and walking performance. In this study, although the primary purpose of Pilates is not to increase exercise capacity, our results have shown that it may also increase exercise capacity. When the literature is analyzed, there is no study investigating the effect of Pilates training on exercise capacity in PwPD. These results are another unique aspect of our study.

Prevalence of fatigue has been reported between 33% and 58% in PD, and it is one of the most common non-motor symptoms.[41] Although

Table 3. A comparison of the previous and subsequent measurements of parameters for the Control Group (N=17).

		Before	After	p
Core Muscle Thickness (d)				
M. Transversus Abdominus, (mm)				
Resting position	Right	4.31±0.80	4.23±0.76	0.203 (a)
	Left	4.45±0.83	4.48±0.86	0.539 (a)
Abdominal Drawn-in	Right	5.40±1.03	5.39±0.94	0.894 (a)
	Left	5.79±1.22	5.75±1.25	0.712 (a)
M. Multifidus, (mm)				
Resting position	Right	21.10±2.04	21.40±2.14	0.729 (a)
	Left	21.59±1.99	21.97±3.05	0.586 (a)
Abdominal Drawn-in	Right	20.70±2.13	21.52±2.05	0.303 (a)
	Left	20.85±1.37	21.82±1.90	0.114 (a)
Core Power (e)				
Sit-up (repetition/30 s)		4.00 (0.00-7.00)	4.64 (0.00-6.00)	0.250 (b)
MPT (repetition/30 s)		5.76 (0.50-9.00)	6.23 (0.50-10.50)	0.119 (b)
Core Endurance (e)				
Side Bridge Test (s)	Right	6.52 (0.00-12.50)	6.00 (0.00-12.50)	0.496 (b)
	Left	5.23 (0.00-8.50)	5.31 (0.00-8.00)	0.777 (b)
Trunk Flexor Test (s)		1.64 (0.00-2.50)	1.29 (0.00-2.00)	0.084 (b)
Prone Bridge (s)		14.17 (3.00-26.00)	15.11 (4.50-25.00)	0.152 (b)
Five Times Sit to Stand Test (5XSST) (sec) (d)		18.47±3.89	18.05±4.26	0.300 (a)
Berg Balance Scale (BBS) (0-56) (d)		51.64±3.49	52.17±3.45	0.095 (a)
Time Up and Go Test (TUG) (sec) (e)		13.29 (11.00-15.00)	12.64 (11.00-14.00)	0.091 (b)
6-Minute Walk Test (6-MWT) (d)				
Distance (m)		378.18±60.65	371.76±65.98	0.233 (a)
Maximal heart rate reached (%)		58.84±3.00	58.76±3.02	0.079 (a)
PFS-16 (16-80) (d)		47.64±8.99	46.88±8.67	0.301 (a)
UPDRS-II (0-52) (e)		11.05 (6.00-14.50)	11.11 (6.00-15.50)	0.917 (b)
PDQ-39 (0-156) (d)		42.76±16.50	39.41±18.14	0.006 (a)

*p<0.05. (a): Independent Samples t-Test. (b): Mann–Whitney U Test. (d): Mean±SD. (e): Median (IQR). MPT: Modified push-up test. PFS-16: Parkinson's Disease Fatigue Scale. UPDRS-II: Unified Parkinson's Disease Rating Scale-Motor assessment subscale. PDQ-39: Parkinson's Disease Quality of Life Questionnaire-39.

few studies have shown that exercise approaches reduce fatigue in PD,[42,43] there is no study yet examining the effect of Pilates on fatigue. This study is the first to show that Pilates reduces the fatigue level and the effect of fatigue on daily functions. We think that the improvement in muscle strength and endurance in the core and extremities, balance, mobility, and exercise capacity is related to the reduction of fatigue and the development of ADL skills.

In current study, it was observed that the QoL in the Pilates group more improved than the control group after the training. Cancela et al.[17] examined the feasibility and effectiveness of 12-week Pilates in 16 patients with mild and moderate PH. They stated that Pilates could be applied as a useful rehabilitation strategy to improve the QoL in PD. It can be said that the improvements in the QoL in PwPD are related to the improvements in physical performance and fatigue in our study. In addition, we think that the physiological benefits of exercise and its contribution to the mood of the individual may have been effective in the developments in the groups, too.

There was no significant improvement in the functional strength of the lower extremity, balance, walking performance, and exercise capacity in the control group. While the Pilates group performed the exercises under the guidance of a therapist, the control group applied it as a home program. In addition, although the control group with a home program was followed, the exercises may not have been done properly. The observation that the patients in the Pilates group increased their compliance with exercise and performed the exercises properly supports the improvements achieved.

Limitations

This study had some limitations. Firstly, all participants were people with a mild-to-moderate stage of PD. Therefore, the results cannot be generalized in terms of an advanced stage of the disease. Second, there was no long-term follow-up. Future studies may be planned more comprehensively considering the limitations of this study.

Conclusion

This study revealed that Pilates improves the core muscle thickness, core stability, lower extremity functional muscle strength, balance, functional mobility, functional exercise capacity, fatigue, ADL, and QoL. Therefore, Pilates may be suggested as an exercise method for PwPD.

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ORIGINAL ARTICLE

Diyafragmatik solunum egzersizlerinin fetal sağlık kaygısı ve prenatal stres ile baş etmeye etkisi

Effect of diaphragmatic breathing exercises on fetal health anxiety and coping with prenatal stress

Esra SABANCI BARANSEL[1], Sümeyye BARUT[2]

Öz

Amaç: Bu çalışma, gebelikte diyafragmatik solunum egzersizlerinin fetal sağlık kaygısı ve prenatal stres ile baş etme üzerine etkisini belirlemek amacıyla yapılmıştır.

Yöntem: Bu randomize kontrollü çalışma, Türkiye'nin doğusundaki bir aile sağlığı merkezinde yürütülmüştür. Araştırmanın örneklemini 108 gebe (deney grubu, 54; kontrol grubu, 54) oluşturmuştur. Deney grubuna bir defa yüz yüze ve devamındaki iki hafta süresince haftada 2 gün görüntülü telefon görüşmesi ile toplamda 5 defa diyafragmatik solunum egzersizleri uygulandı. Kontrol grubuna herhangi bir müdahale uygulanmadı. Verilerin toplanmasında Revize Prenatal Stresle Başa Çıkma Ölçeği, Fetal Sağlık Kaygı Envanteri kullanıldı.

Bulgular: Deney grubunda Revize Prenatal Stresle Başa Çıkma Ölçeği alt boyutlarından Planlama- Hazırlık (2,16 vs 2,17; p<,05) ve Manevi-Olumlu Başa Çıkma (2,55 vs 2,59; p<,05) alt boyut ortalama puanları kontrol grubuna göre anlamlı derecede yükselirken, kaçınma alt boyutu (2,61 vs 2,68; p<,05) ortalama puanları anlamlı derecede azaldı. Benzer şekilde deney grubu fetal sağlık anksiyetesi ortalama puanları kontrol grubuna göre önemli ölçüde azaldı (10,35 vs 13,57; p<,05).

Sonuç: Diyafragmatik solunum egzersizinin, gebelerin stresle etkin bir şekilde başa çıkmayı geliştirmede etkili olduğu ve gebelerin fetal sağlık kaygısını azalttığı belirlendi. Sağlık profesyonelleri, gebelerin fetal sağlık kaygılarını azaltmak ve işlevsel başa çıkma tarzlarını kullanabilmelerini desteklemek için diyafragmatik solunum egzersizini kullanabilirler.

Anahtar kelimeler: Gebelik, Solunum egzersizi, Fetal sağlık kaygısı, Stres, Başa çıkma, Ebelik bakımı.

Abstract

***Purpose**: This study was conducted to determine the effect of diaphragmatic breathing exercises on coping with fetal health anxiety and prenatal stress during pregnancy.*

***Methods:** This randomized controlled study was carried out at a family health center in eastern Turkey. The study sample consisted of 108 pregnant women (experimental group, 54; control group, 54). Diaphragmatic breathing exercises were applied to the experimental group, once face to face and 5 times in total, via video phone call 2 days a week for the following two weeks. Those in the control group received no intervention. Data were collected using the Revised-Prenatal Coping Inventory (NuPCI) and the Fetal Health Anxiety Inventory (FHAI).*

***Results:** The mean scores on planning-preparation (2.16 vs 2.17; p<.05) and spiritual-positive (2.55 vs 2.59; p<.05) subscales of NuPCI significantly increased and the mean score of avoidance (2.61 vs 2.68; p<.05) significantly decreased in the experimental group compared to the control group. Similarly, the mean scores of fetal health anxiety significantly decreased in the experimental group compared to the control group (10.35 vs 13.57; p<.05).*

***Conclusion:** Diaphragmatic breathing exercises were found to be effective in improving effective coping styles for stress and reducing fetal health anxiety during pregnancy. Health professionals can use diaphragmatic breathing exercise to reduce pregnant women's fetal health anxiety and support pregnant women in their functional coping styles.*

***Keywords:** Pregnancy, Breathing exercises, Fetal anxiety, Stress, Coping, Midwifery care.*

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INTRODUCTION

Pregnancy is a natural event that many women look forward to have with happiness and excitement, but it can be challenging for some women. In addition to physiological and psychological changes occurring during pregnancy, the readiness for a new life, changes in body image perception, fear of becoming a parent, uncertainties about childbirth, fears about the baby's development and survival can cause stress in pregnant women.[1] Moreover, stressors during pregnancy such as economic problems, epidemics, and natural disasters can contribute to anxiety about both maternal and fetal health and cause significant stress.[2-5] Stress is commonly observed during pregnancy and ranks high among stressful life events.[6-9]

The negative effects of stress on human health are well-known. Both maternal and fetal health and their immune responses are sensitive to stress during pregnancy. High cortisol levels can lead to changes in their immune responses, suppressing the immune system and causing complications such as premature birth.[10,11] Stress during pregnancy has been associated with negative pregnancy outcomes such as spontaneous abortion, pregnancy-induced hypertension, placental abnormalities, difficult labor, operative deliveries, low APGAR score, low birth weight, fetal death, postpartum depression, and long-term health problems such as cerebral palsy, neurodevelopmental delay, vision and hearing problems.[12-15]

Although many pregnant women are exposed to stress, not all women who experience stress have negative pregnancy outcomes. The positive or negative experiences of pregnant women during pregnancy, their styles of coping with these experiences and stress, and the stressors they are exposed to affect whether the stress will disrupt their body balance and cause negative outcomes such as illness.[16-18] The style of coping with stress is determinant in adapting to stressful events. Functional styles of coping with stress can reduce negative effects of stress, while ineffective coping styles can increase health risks.[19] Coping styles of pregnant women with stress may vary, including functional coping styles such as having self-confidence, seeking social support, planning, and spiritual readiness and ineffective coping styles such as helplessness and avoidance.[20,21] Considering the importance of coping with stress, understanding how pregnant women cope with stress and intervening to develop their styles of coping with stress may be useful in reducing stress during pregnancy. Various non-pharmacological methods such as relaxation exercises, yoga, biofeedback, massage therapy, acupuncture, and music therapy may be useful in reducing stress during pregnancy.[17,22] However, there is no study about the effect of non-pharmacological methods in pregnancy on coping styles with stress. Some studies have reported that diaphragmatic breathing exercises increase quality of life and oxygenation and have a positive effect on anxiety.[23,] Therefore, both physical and psychological effects of diaphragmatic breathing exercises in pregnant women may positively affect their styles of coping with stress and reduce fetal health anxiety. For this reason, this study aimed to determine the effect of diaphragmatic breathing exercises, on coping with fetal health anxiety and prenatal stress.

METHODS

Design

This randomized controlled study was conducted with pregnant women who were randomly assigned to experimental and control groups, and those who were assigned to the experimental group received diaphragmatic breathing exercises.

For conducting the study, an ethical approval was obtained from the Inonu University Health Sciences Non-Invasive Clinical Research and Publication Ethics Committee (Decision No: 2022/3797). Additionally, a Clinical Trials number was received from ClinicalTrials.gov (NCT05954754).

Participants

The sample for the study consisted of pregnant women who referred to a family health center (FHC) in the center of a city in eastern Turkey. Healthy pregnant women were monitored by midwives and family physicians at the FHC, while high-risk pregnancies were referred to hospitals.

The inclusion criteria for this study were as follows: (1) being pregnant women in their second and third trimesters (between 14-36 weeks);[24,25] (2) being ≥18 years old; (3) having no medical pregnancy complications; (4) having no diagnosed mental illness; (5) having no fetal anomaly diagnosis; (6) using a smartphone. The exclusion criteria from the study are as follows: (1) receiving a diagnosis of any chronic disease during the research process and starting medication for the chronic disease; (2) detection of a fetal risk during the research process.

A web-based software program was used to calculate the sample size for the study, considering the mean coping with stress during pregnancy score, which was the primary dependent variable. The coping with stress during pregnancy score reported by Faramarzi et al. was used as a reference (mean=2.28, standard deviation=0.54). The sample size was calculated to be 54 for each group (54 for the experimental group, 54 for the control group), assuming a 1-point increase in the mean coping with stress during pregnancy score after the intervention, with a two-sided significance level of 5%, 95% confidence interval, and 80% power. Randomization was used to assign pregnant women to either the intervention or control group. The Numbers section of the random.org website was used for randomization, and pregnant women who applied to the FHC were assigned to groups based on their order of arrival to the FHC, with the first and second women assigned to the experiment and control groups, respectively. The groups were allocated by a draw, where the number 1 was assigned to the experiment group and the number 2 was assigned to the control group. The same method was used to assign pregnant women to the experimental or control group until the desired sample size was reached. Figure 1 shows the sample selection process, which was conducted according to the CONSORT criteria.

Measures

The data were collected by the researchers after routine check-ups of pregnant women between November 2022 and June 2023. After pregnant women were informed about the study, the researchers asked questions to those who agreed to participate in the study, and their answers were marked on the data collection forms. The primary outcome of the study, coping with stress during pregnancy, was evaluated using the Revised-Prenatal Coping Inventory (NuPCI). The secondary outcome, fetal health anxiety, was measured using the Fetal Health Anxiety Inventory (FHAI).

A personal information form was created by the researchers in line with the literature to determine pregnant women's sociodemographic (age, education level, employment status, and income level) and pregnancy characteristics (trimester, gravida, and planned pregnancy).

The NuPCI was developed by[26] and its Turkish validity and reliability study was conducted by Bal et al. The scale measures pregnant women's coping styles and perceptions of stress. It consists of 30 items and three subscales: Planning-preparation, Avoidance, and Spiritual-positive. This is a 5-point Likert-type scale, scoring from 0 (never) to 4 (very often). Higher planning-preparation and spiritual-positive subscale scores and lower avoidance subscale scores indicates higher coping with stress. Bal et al. reported the Cronbach's alpha reliability coefficient for the planning-preparation, avoidance, and spiritual-positive subscales as 0.83, 0.57, and 0.69, respectively.[27] In this study, the Cronbach's alpha reliability coefficient for the planning-preparation, avoidance, and spiritual-positive subscales were found to be 0.81, 0.66, and 0.72, respectively.

The FHAI was developed by Reiser and Wright and its Turkish validity and reliability study was conducted by Gökbulut et al.[5] The scale measures pregnant women's anxiety related to the fetus' health. It consists of 14 items, and each item consists of four statements that best capture the women's experiences in the previous weeks. This is 4-point Likert-type scale, scoring from 0 (no symptoms) to 3 (severe symptoms). The sum of item scores gives the total fetal health anxiety score, and as the total score increases, the level of fetal health anxiety also increases. The Cronbach's alpha reliability coefficient of the scale was 0.85.[5] In this study, the Cronbach's alpha reliability coefficient of the scale was found to be 0.89.

Intervention

In the present study, the baseline data were collected by the researchers through face-to-face interviews in the counseling room of the FHC. Two weeks later, the post-treatment data were obtained using the same method. After the baseline data were collected, diaphragmatic

breathing exercise training was given individually to each pregnant women in the experimental group by one of the trained researchers, named E.S.B. At the end of the training, the pregnant women performed the exercise individually under the supervision of the researcher. Data collection, training and application lasted around 40 minutes. After the first application, the researcher had the pregnant woman repeat the application via video call, 2 days a week for two weeks. The video calls were made on the day and time when pregnant women were suitable, and each application lasted around 10 minutes. Thus, a total of five diaphragmatic breathing exercises were applied to pregnant women in the experimental group during two weeks. Pregnant women continued to do breathing exercises on their own for a total of 20-30 minutes a day, as tolerated (about ten minutes each), every day for two weeks. Although the optimal application time of breathing exercises is not yet determined in the literature, 2-3 sessions a week are planned for outpatients, while 5 sessions a week can be planned for inpatients.[28] No intervention was applied to pregnant women in the control group by the researchers.

In order for pregnant women to apply the correct technique in diaphragmatic breathing exercises, they were asked to first rest for 1-2 minutes in a supine position with pillows under their heads and support from their knees on a flat surface. Their one hand was placed on the abdomen and the other on the upper part of the chest wall. While inhaling, their hand on the abdomen moved upwards, while the other hand remained as still as possible. While exhaling, their hand on the abdomen moved downwards, while the other hand remained as still as possible. They were asked to breathe slowly, deeply, and without causing fatigue. They were told to breathe through the nose and exhale through the mouth. To prevent the risk of hyperventilation, they were instructed to slowly exhale all the air using controlled expiration. After they performed diaphragmatic breathing exercises correctly, the exercises were repeated in a sitting position. In the two-week exercise program, the exercises were performed in a seated position.[28,29]

Statistical analysis

For the statistical analysis, the data were assessed using SPSS 25.0 for Windows software (SPSS, Chicago, IL, USA). Descriptive statistical values, numbers, percentages, means and standard deviations were used for the analysis. Comparisons of the categorical variables between groups were carried out using the chi-squared test. An independent-samples t-test was used to make comparisons between the experimental and control groups; a paired-samples t-test was used to make comparisons intra-groups. If the results of the t-tests were significant, effect sizes were computed using Cohen's d to identify significant differences. The statistical significance level was considered as $p<0.05$.

RESULTS

The study was conducted with a total of 108 pregnant women, including 54 in the experimental group and 54 in the control group (Figure 1). Their characteristics, including age, education level, employment status, income level, trimester, gravid, and planned pregnancy, were similar in both groups ($p>0.05$) (Table 1).

Table 2 shows the pre-test and post-treatment NuPCI subscales mean scores. The planning-preparation and spiritual-positive mean scores of pregnant women in the experimental group significantly increased after the intervention (Cohen's d=0.693, Cohen's d=1.109, respectively; $p<0.05$), while their avoidance mean score significantly decreased (Cohen's d=0.443; $p<0.05$). The difference between the groups' mean scores after the intervention was statistically significant in favor of those in the experimental group (Cohen's d=0.665, Cohen's d=0.812, Cohen's d=0.821, respectively; $p<0.05$) (Table 2).

Table 3 presents the pre-test and post-treatment FHAI total mean scores. The FHAI mean score of pregnant women in the experimental group significantly decreased after the intervention ($p<0.05$; Cohen's d=0.487), and the difference between the groups' mean scores was statistically significant in favor of those in the experimental group ($p<0.05$; Cohen's d=0.651) (Table 3).

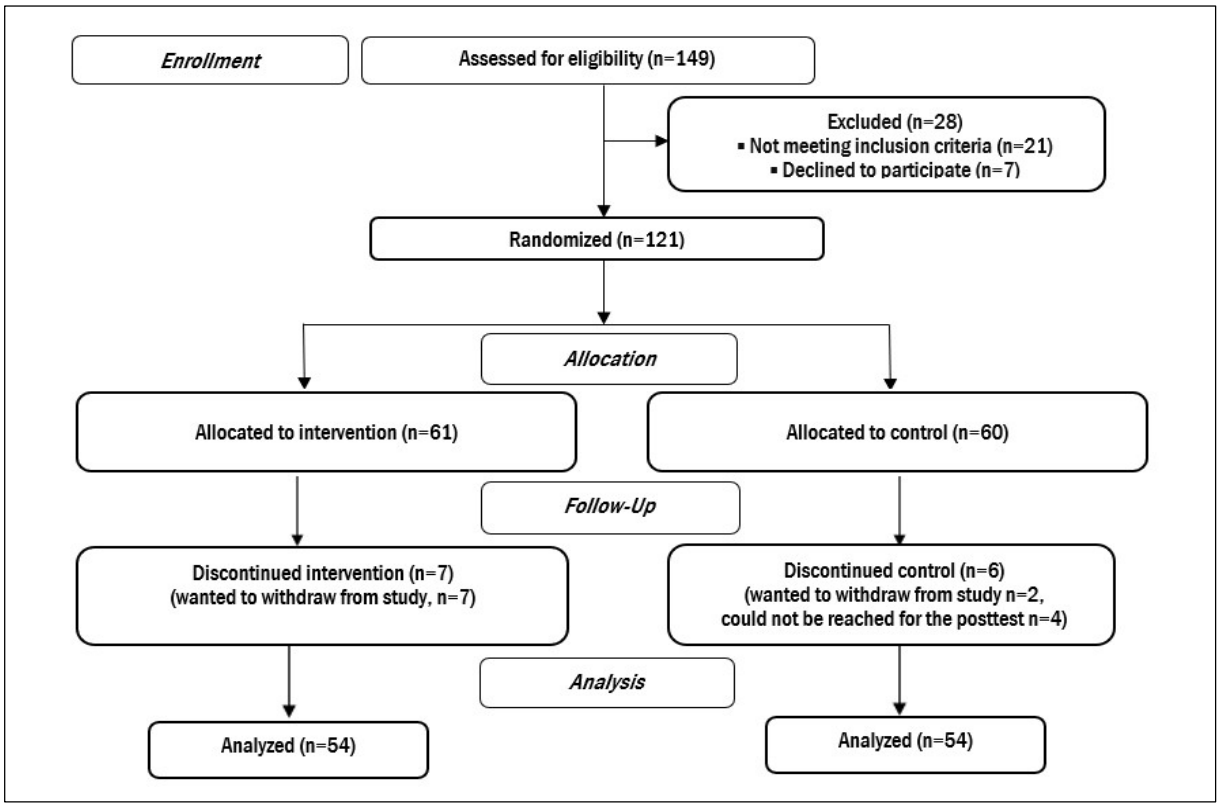

Figure 1. CONSORT diagram of the participants for each stage in the study.

Table 1. Characteristics of the participants.

	Experimental Group (N=54)	Control Group (N=54)	
	n (%)	n (%)	p
Age (years)			
≤ 25	18 (33)	15 (28)	0.531
≥26	36 (67)	39 (72)	
Education level			
High school and below	42 (78)	34 (63)	0.092
University or above	12 (22)	20 (37)	
Employment status			
Employed	18 (33)	12 (22)	0.197
Unemployed	36 (67)	42 (78)	
Income rate			
Low	8 (15)	13 (24)	0.224
Middle	46 (85)	41 (76)	
Trimester			
II.	13 (24)	18 (33)	0.288
III.	41 (76)	36 (67)	
Gravid			
Primigravid	22 (41)	19 (35)	0.552
Multigravid	32 (59)	35 (65)	
Planned pregnancy			
Yes	40 (74)	42 (78)	0.653
No	14 (26)	12 (22)	

Chi-square test.

Table 2. Comparison of the Pre- and Post-treatment Revised-Prenatal Coping Inventory (NuPCI) subscales mean scores of pregnant women in Experimental and Control groups.

	Pretest	Posttest		
	Mean±SD	Mean±SD	p (a)	Effect size (d)
Planning-preparation				
Experimental Group	1.97±0.64	2.39±0.57	0.001*	0.7
Control Group	2.16±0.73	2.12±0.67	0.497	
p (b)	0.164	0.027*		
Effect size (d)		0.665		
Avoidance				
Experimental Group	2.51±0.55	2.25±0.62	0.028*	0.4
Control Group	2.61±0.50	2.68±0.42	0.260	
p (b)	0.293	<0.001		
Effect size (d)		0.812		
Spiritual-positive				
Experimental Group	2.44±0.57	3.00±0.43	<0.001	1.1
Control Group	2.55±0.60	2.59±0.56	0.594	
p (b)	0.330	<0.001		
Effect size (d)		0.821		

* p<0.05. (a): Paired t Test. (b): Independent t Test. (d): Cohen d.

Table 3. Comparison of the Pre- and Post-treatment the Fetal Health Anxiety Inventory (FHAI) total mean scores of pregnant women in experimental and control groups.

	Pretest	Posttest		
	Mean±SD	Mean±SD	p (a)	Effect size (d)
Experimental Group	13.00±6.64	10.35±3.85	0.013*	0.4
Control Group	13.85±7.70	13.57±5.83	0.676	
p (b)	0.540	<0.001		
Effect size (d)		0.6		

* p<0.05. (a): Paired t test. (b): Independent t test. (d): Cohen d.

DISCUSSION

The results of this study indicate that diaphragmatic breathing exercises applied during pregnancy may be an effective approach to alleviate fetal health concerns and improve coping with stress.

Pregnant women in the experimental group were found to use functional coping strategies, such as planning and positive emotional coping strategies, more frequently, and to utilize non-functional coping strategies, such as avoiding maladaptive coping behaviors, less frequently after the intervention. There was a significant difference between the experimental and control groups in terms of using functional and non-functional coping strategies. The positive changes in the pregnant women's coping styles suggest that diaphragmatic breathing exercises may be an effective method for coping with stress during pregnancy. In the literature, there is no study about the effect of diaphragmatic breathing exercises on coping styles in pregnant women, but studies on the effect of interventions on stress are more common. A study applied breathing exercises to pregnant women and reported that breathing exercises were effective

in reducing stress in pregnant women.[30] Another study applied breathing exercises to pregnant women during the latent phase of labor, and reported that breathing exercises were an effective method for reducing anxiety during labor.[31] Another study of women with gestational diabetes reported that breathing exercises reduced depression and stress.[32] Studies have shown that breathing exercises are an appropriate method for reducing stress, and support our study results. Breathing exercises regulate oxygen exchange, metabolic rate, lower blood pressure, and help improve cognitive functions such as problem solving in pregnant women.[33] In another study, it was reported that breathing exercises and muscle relaxation exercises increased the sense of control and reduced stress in pregnant women.[34] Therefore, diaphragmatic breathing exercises applied to pregnant women in the experimental group in our study allowed them to develop appropriate coping strategies by improving their cognitive functions and increasing the sense of control.

In the present study, fetal health anxiety decreased significantly in the experimental group compared to the control group. Pregnant women experience anxiety for various reasons during pregnancy, including concerns about fetal health and life.[35] Breathing exercise is a form of relaxation technique, and its positive effect on anxiety is well known.[36] Diaphragmatic breathing exercises may alleviate fetal health concerns through this effect. A study applied breathing exercises to pregnant women for childbirth and reported that breathing exercises reduced state anxiety in pregnant women.[30] Another study reported that relaxation exercises such as breathing exercises reduce the rate of hospital admission and have a positive effect on the emotional state of the mother.[37] Pregnant women's ability to maintain their pregnancy healthy, cope with pregnancy-related problems, and their coping mechanisms are closely related to each other.[15] Decreased fetal health anxiety in our study may be because pregnant women in the experimental group acquired positive coping skills after the intervention, which allowed them to improve their ability to cope with their existing anxieties during pregnancy by developing their problem-solving skills.[38] These findings showed that diaphragmatic breathing exercise helps pregnant women cope with anxiety and reduces their concerns about fetal health. Accordingly, the available evidence suggests that diaphragmatic breathing exercise can be used among non-medical methods to alleviate fetal health anxiety in pregnant women.

Limitations

This study has some limitations. Firstly, since the study was conducted with pregnant women who applied to an FHC, its results cannot be generalized to the entire population. Secondly, another limitation is that they could not be followed up from the first trimester of pregnancy. Thirdly, coping styles were evaluated using a scale with only three sub-dimensions, which may have created limitations in evaluating coping styles. However, the use of a scale specific to pregnant women and its correlation with scales used for coping with stress in the general population may have provided advantages in evaluating coping styles of pregnant women. Despite all limitations, this study will guide future studies in demonstrating the effectiveness of diaphragmatic breathing exercises in coping with stress and alleviating fetal health anxiety during pregnancy.

Conclusion

This study suggests that diaphragmatic breathing exercises applied during pregnancy contribute to pregnant women's adoption of functional coping styles with stress and reduce fetal health anxiety. In this regard, the use of breathing exercises, a non-pharmacological method, can be recommended for pregnant women to cope effectively with stress and adopt functional coping styles.

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ORIGINAL ARTICLE

Gerilim tipi baş ağrısı olan bireylerde temporomandibular gevşetme ve miyofasial gevşetme tekniklerinin yaşam kalitesi, depresyon ve baş ağrısı üzerine etkisi

The effect of temporomandibular release and myofascial release techniques on quality of life, depression, and headache in ındividuals with tension-type headache

Ayşe ÖZ[1], Ayça ARACI[2], Ahmet ÖZŞiMŞEK[3], Hanifegül TAŞKIRAN[1], Burak YULUĞ[3]

Öz

Amaç: Gerilim tipi baş ağrısı (GTBA) toplumda sıklıkla görülmektedir. Çalışmamızın amacı GTBA olan bireylerde temporomandibular eklem (TME) Yumuşak Doku Teknikleri (TME-YDT) ve miyofasial gevşetme (MFG) tekniklerinin etkinliğini incelemektir.

Yöntem: Uluslararası Baş Ağrısı Derneğinin Baş ağrısı sınıflandırması (ICHD-3)'na göre 18-65 yaşları arası GTBA tanısı alan 73 gönüllü birey dahil edildi. Bireyler randomizasyon metoduna göre Grup 1; TME-YDT, Grup 2; MFG Grubu ve Grup 3; Kontrol Grubu olmak üzere 3'e ayrıldı. Baş ağrısı, Headache Impact Test-6(HIT-6) ile; TMED Fonseca Ölçeği ile; Temporomandibular EHA cetvel yardımı ile; servikal EHA gonyometre ile; yaşam kalitesi, SF-36 Yaşam Kalite Ölçeği ile; depresyon, Beck Depresyon Ölçeği (BDÖ) ile; Anksiyete, Beck Anksiyete Ölçeği (BAÖ) ile değerlendirildi. Değerlendirmeler tedavi öncesi ve 4 haftalık tedavi sonunda yapıldı. Grup 1'e TME- YDT (anterior kaudal glide, masseter ve medial pterygoid kaslarına yumuşak doku mobilizasyonu), Temporal ve Suboksipital kaslara miyofasial gevşetme tekniği uygulandı. Grup 2'ye grup 1'e yapılan uygulamalara ek olarak Trapez, Rhomboid, Levator Scapula ve Sternocleidomasteideus kaslarına ve derin posterior servikal fasya gevşetme teknikleri uygulandı.

Bulgular: Hem TME hem de MFG gruplarının FONSECA ve HIT6 total skorlarında meydana gelen değişimin kontrol grubuna göre anlamlı şekilde yüksek olduğu görüldü($p<0,05$).

Sonuç: GTBA tedavisinde TME yumuşak doku tekniklerinin miyofasial teknikler kadar etkili olduğu bulundu.

Anahtar kelimeler: Yaşam kalitesi, Gerilim tipi baş ağrısı,Temporamandibular eklem, Anksiyete, Normal eklem hareketi.

Abstract

***Purpose**: Tension-type headache (TTH) is commonly observed in the community. The aim of our study is to investigate the effectiveness of Temporomandibular Joint Soft Tissue Techniques (TMD-STT) and Myofascial Release (MFR) techniques in individuals with TTH.*

***Methods:** Seventy-three voluntary individuals between the ages of 18-65 diagnosed with TTH according to the International Classification of Headache Disorders (ICHD-3) were included. Participants were divided into three groups based on randomization: Group 1; TMD-STT, Group 2; MFR Group, and Group 3; Control Group. Headache was assessed using the Headache Impact Test-6 (HIT-6); TMJ with the Fonseca Scale; Temporomandibular Range of Motion with a goniometer; quality of life with the SF-36 Quality of Life Scale; depression with the Beck Depression Scale (BDS); and anxiety with the Beck Anxiety Scale (BAS). Evaluations were conducted before treatment and at the end of 4 weeks. Group 1 received TMD-STT (soft tissue mobilization to anterior caudal glide, masseter, and medial pterygoid muscles) and Myofascial Release technique to temporal and suboccipital muscles. In addition to the applications in Group 1, Group 2 received deep posterior cervical fascia relaxation techniques for Trapezius, Rhomboid, Levator Scapula, and Sternocleidomastoid muscles.*

***Results:** Significant improvement in FONSECA and HIT-6 total scores was observed in both TMD-STT and MFR groups compared to the control group ($p<0.05$).*

***Conclusion:** TMD soft tissue techniques were found to be as effective as myofascial techniques in the treatment of TTH.*

***Keywords:** Quality of life, Tension-type headache, Temporomandibular joint, Anxiety, Normal joint movement.*

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INTRODUCTION

One of the most common complaints in society is headaches, significantly affecting the quality of life for individuals. The rate of individuals experiencing a headache at least once in their lifetime is over 90% in society (93% for men and 99% for women). Headaches are fundamentally classified into two main groups: "primary type headaches and secondary type headaches".[1] Among headaches, tension-type headache (TTH) is defined as a primary type of headache,[2] with a lifetime prevalence of 46% in adults.[3] Studies in the literature have reported that temporomandibular joint dysfunction (TMJD) and headaches are "comorbid diseases," suggesting that the presence of one will increase the symptoms of the other, and if both disorders occur, symptoms start earlier than expected.[4,5]

Literature studies have proven that TMJD affects headaches, jaw stiffness, and functionality in jaw movements. However, TMJD increases with stress and has been reported to cause significant difficulties in performing daily activities.[3] In this context, various studies have shown a strong correlation between pain during mandibular movements, headaches, joint sounds, pain in the temporomandibular area, sleep quality impairment, depression, and anxiety.[5,6]

Additionally, from a diagnostic perspective, the International Classification of Headache Disorders has listed the relationship between TMJD and headaches under item 11.7, where headaches are attributed to temporomandibular disorders.[3] As mentioned above, studies have already shown the relationship between temporomandibular dysfunction and tension-type headache (TTH).[7]

The literature includes studies demonstrating the effectiveness of manipulative treatment methods for tension-type headaches,[8–10] osteopathic,[11] and craniosacral therapy methods.[12,13] However, no studies have been found examining the effectiveness of manipulative treatment methods for the temporomandibular joint in alleviating TTH. Based on these data, the main aim and hypothesis of our study are to examine the effects of Temporomandibular Joint Soft Tissue Techniques (TMJ-STT) and myofascial release techniques (MRT) on the quality of life, depression, and headache in individuals with tension-type headache. Our secondary purpose is to compare the effectiveness of Temporomandibular Joint Soft Tissue Techniques (TMJ-STT) alone and Temporomandibular Joint Soft Tissue Techniques (TMJ-STT)+Myofascial Release Technique (MRT) in individuals with TTH.

METHODS

The study received approval from the institutional review board of Alanya Alaaddin Keykubat University's ethical committee (No:10354421-2021/07-08). The trial was registered on www.ClinicalTrials.gov (identifier:NCT05058573). We adhered to the CONSORT reporting guidelines for pilot and feasibility studies.

Individuals

Fifty volunteers aged 18-65 years who met the inclusion criteria were included in this study.

Inclusion and exclusion criteria and search strategy

The inclusion criteria were as follows: (1) Being diagnosed with Tension-Type Headache (TTH) by a neurology specialist according to the International Classification of Headache Disorders (ICHD-3) criteria,[14] (2) Being able to read and understand Turkish, (3) Not receiving medical treatment in the previous 1 year.

The exclusion criteria were as follows: (1) Having received physical therapy for TMJD in the previous 6 months, (2) Having neurological disorders, (3) Having congenital disease, (4) Depression, (5) Having mental problems, (6) Having a history of cervical or cranial surgery, (7) Having received corticosteroid therapy within the previous year, (8) History of facial trauma (those with a history of facial paralysis), advanced level cervical disc herniation (protrusion and sequestered disc), ankylosing spondylitis, rheumatoid arthritis, or systemic diseases such as fibromyalgia, (9) Having communication problems.

Sample size

According to the conducted power analysis, it was observed that the effect size obtained in the reference study is at a strong level (d=1.524). Considering that a lower level of effect size could also be obtained (f=0.4), the power analysis

results indicate that with a minimum of 66 participants (at least 22 participants for each group), a power of 80% can be achieved at a 95% confidence level. To account for the possibility of participants dropping out of the study, 25 voluntary individuals were included in each group. In the referenced randomized clinical trial study, a total of 30 women diagnosed with Tension-Type Headache (GTBA) were selected using a simple non-probability sampling method.[1]

Design

According to the power analysis conducted prior to the study, it was determined that the inclusion of 66 individuals would be sufficient. However, 87 individuals presenting with headaches and diagnosed with Tension-Type Headache were evaluated at the clinic. Six individuals were excluded from the study as they did not meet the inclusion criteria. The 81 individuals included in the study were randomly divided into 3 groups using the SPSS computer random number generator: Group-1 (n=27) TMJ Soft Tissue Techniques (TMJ-STT) group; Group-2 (n=27) MRT Group including in TMJ-STT; Group-3 (n=27) was planned as the control group receiving only traditional medical treatment. However, a total of 8 individuals were excluded from the study during the course of the study due to their irregular participation. Our study concluded with the participation of a total of 73 individuals (Figure 1).

The patients included in Group 1 and Group 2 received a total of 8 sessions of manual therapy, 2 sessions per week, for 4 weeks. Individuals included in Group 3 were first evaluated and then regularly asked to continue the medical treatment recommended by the physician. Individuals were re-evaluated 4 weeks later.

Recruitment

After the approval of Alanya Alaaddin Keykubat University Non-Interventional Clinical Research Ethics Committee (Date: 14.04.2021, Number: 10354421-2021/07-08), the research was carried out in accordance with the "Helsinki Declaration".

Manipulative techniques

TMJ soft tissue techniques

For the TMJ Soft Tissue Technique (TMJ-STT), the individual laid supine on the treatment bed. The therapist was positioned at the patient's head-side, facing the patient. The therapist placed her thumb on the upper posterior surface of the teeth and her fingers along the line of the mandible. Caudal anterior gliding, one of the soft tissue release techniques, was applied to the temporomandibular joint. Soft tissue mobilization was performed to the medial pterygoid and masseter muscles. The suboccipital myofascial release technique was applied while the patient was lying in the supine position. The therapist completely relaxed the patient's head and applied cranial pull while her 4th and 5th fingers were in the semi-flexion position. While the patient was lying back, their head was flexed slightly to the right and myofascial release technique was applied to the temporal muscle. The therapist held the fascia steady with one hand, while applying gentle pushes in the caudal direction with the other. Right and left bilateral application was made (Figure 2).

Myofascial release technique

The patient lay face down on the treatment bed. The upper trapezius release technique was applied unilaterally while the patient was lying face down. The myofascial release technique was applied to M. Trapezius M. Rhomboideus, M. Levator Scapulae, and M. Sternocleidomastoid muscles for 3-5 minutes. The deep posterior cervical fascia release technique, was applied while the patient was in the supine position. The therapist completely released the head weight. While all four fingers were in the semi-flexion position, a slight pull was applied from the base of the occiput to the cranial. The deep posterior cervical fascia was relaxed by gently pressing the fingers along the superior direction. The treatment was applied for 20 minutes in both groups (Figure 2).

Measures and data collection

Data collection was conducted from April 2021 to August 2021.

Outcome measures

Cervical region joint movement

Evaluation of the joint range of motion of the cervical region was performed using a "universal goniometer". The Kendall Mc-CREARY mean value of joint range of motion (ROM) was used for measurements. Head flexion-extension and lateral flexion and rotation movements were shown to the patients, in this order. They were then asked to perform these movements and the measurements were recorded.[15]

TMJ range of motion

The maximum amount of mouth opening (M-MO), the maximum amount of assisted mouth opening (A-MO), the amount of painless active mouth opening (P-MO), and the right and left movements of the lower jaw (laterotrusion) were measured using a ruler (mm). Mouth opening was evaluated based on the mean reference values determined by Walker et al. (43.5+-6.1 mm).[15]

TMJ dysfunction classification

The Fonseca Questionnaire was administered to classify TMJD. This questionnaire, developed by Fonseca et al. in the early 1990s, consists of 10 items.[3] There are 3 answer options for each question: 10 points for "yes", 5 points for "sometimes", 0 points for "no". The scores of all items are summed and the severity of temporomandibular joint dysfunction is determined, where 0-15 points indicate no TMJD, 20-40 points indicate mild-TMJD, 45-60 points indicate moderate-TMJD, and 70-100 points indicate severe-TMJD.[14,16]

Depression

Beck Depression Inventory (BDI)

The Beck Depression Inventory, consisting of 21 items, was used to evaluate the psychological status of the individuals.[4,5] Each question consists of 4 options and the individual is asked to choose the one reflecting their mood best. Each item is scored between 0 and 3. High scores reflect poor results. According to the total score obtained, 0-9 points indicate minimal depression, 10-16 points indicate mild depression, 17-29 points indicate moderate depression, and 30-63 points indicate severe depression.[8]

Anxiety

Beck Anxiety Inventory (BAI)

The Beck Anxiety Inventory is an assessment tool that provides information about whether individuals have anxiety symptoms.[6,7] The subjects were asked to answer questions about how much symptoms bothered them when they were anxious or stressed in the previous week. The BAI consists of 21 four-point Likert type items, where 0-points indicates none; 1-point indicates mild- "didn't affect me much"; 2-points indicate moderate- "it wasn't pleasant but I endured", and 3-points indicate severe- "I had a hard time holding on". A range of 8-15 points is expressed as "mild anxiety symptoms", 16-25 points as "moderate anxiety symptoms", and 26-63 points as "severe anxiety symptoms".[17]

Headache

The Headache Impact Test-6 (HIT-6) was used to evaluate the headache symptoms of the patients[18,19]. The HIT-6 consists of 6 items regarding headache severity, the extent of restriction at school, work, or social activities due to headache, psychological status, and changes in cognitive status. The patients were asked to answer 6 questions by choosing the most appropriate option: "always, often, sometimes, rarely, and never", where "always" is 13 points, "often" is 11 points, "sometimes" is 10 points, "rarely" is 8 points, and "never" is 6 points. The total score ranges from 36 to 78, where grade 1 is no influence≤49; Grade 2 is 50-55 points, moderate exposure; Grade 3 is 56-59 points, a significant influence; and, Grade 4 is severe influence, ≥60 points.[20,21]

General quality of life assessment

The 36-Item Short Form Health Survey (SF-36), developed by Ware et al., was used to evaluate the general quality of life of the patients.[22,23] The SF-36 is a questionnaire consisting of 36 items to obtain information about the physical pain, physical state, emotional state, and general health of individuals The general quality of life scale includes 8 sub-parameters, namely, mental health, energy state, bodily pain, physical function, limitation due to physical problems, limitation due to emotional problems, social function, and general health status. The total score ranges from 0 to 100 points. High scores indicate that the individual is in good health.[24]

Statistical analysis

Data were analyzed with SPSS 25.0 (IBM SPSS Statistics 25 software (Armonk, NY: IBM Corp) package program. Continuous variables are expressed as mean ± standard deviation, median (25th and 75th percentiles), and min-max values. Categorical variables are expressed as numbers and percentages. The conformity of the data to the normal distribution was examined using the Shapiro Wilk test. In independent group analysis, One Way Analysis of Variance (post hoc: Tukey test) was used when parametric test assumptions were met. When parametric test assumptions were not met, Kruskal Wallis Analysis of Variance (post hoc: Mann Whitney U test with Bonferroni correction) was used. When the parametric test assumptions were met in comparing the

differences between the measurements, the t-test was used in the dependent groups and the Wilcoxon Paired-Sample Test was used when parametric test assumptions were not met. The Chi-square test was used to examine the differences between categorical variables. $p<0.05$ was considered statistically significant.[9]

RESULTS

In our study, 87 individuals aged 18-65 years presenting with headaches and diagnosed with Tension-Type Headache were evaluated at the clinic. Six individuals were excluded from the study as they did not meet the inclusion criteria. The 81 individuals included in the study were randomly divided into 3 groups using the SPSS computer random number generator: Group-1 (n=27) TMJ Soft Tissue Techniques (TMJ-STT) group; Group-2 (n=27) MRT Group including in TMJ- STT; Group-3 (n=27) was planned as the control group receiving only traditional medical treatment. However, a total of 8 individuals were excluded from the study during the course of the study due to their irregular participation. Our study concluded with the participation of a total of 73 individuals (Figure 1).

The results of the passive assessment of the maximum mouth opening amount (M-MO) and painless active mouth opening amount (P-MO) before and after treatment did not show a significant difference among the three groups. When the changes in Group 1 and Group 2 were examined over the 4 weeks before and after treatment, a statistically significant increase was observed in both the maximum mouth opening amount (M-MO) and the passive assisted mouth opening amount (P-MO) ($p<0.05$). No change was observed in Group 3 ($p>0.05$) (Table 2). When the changes in the

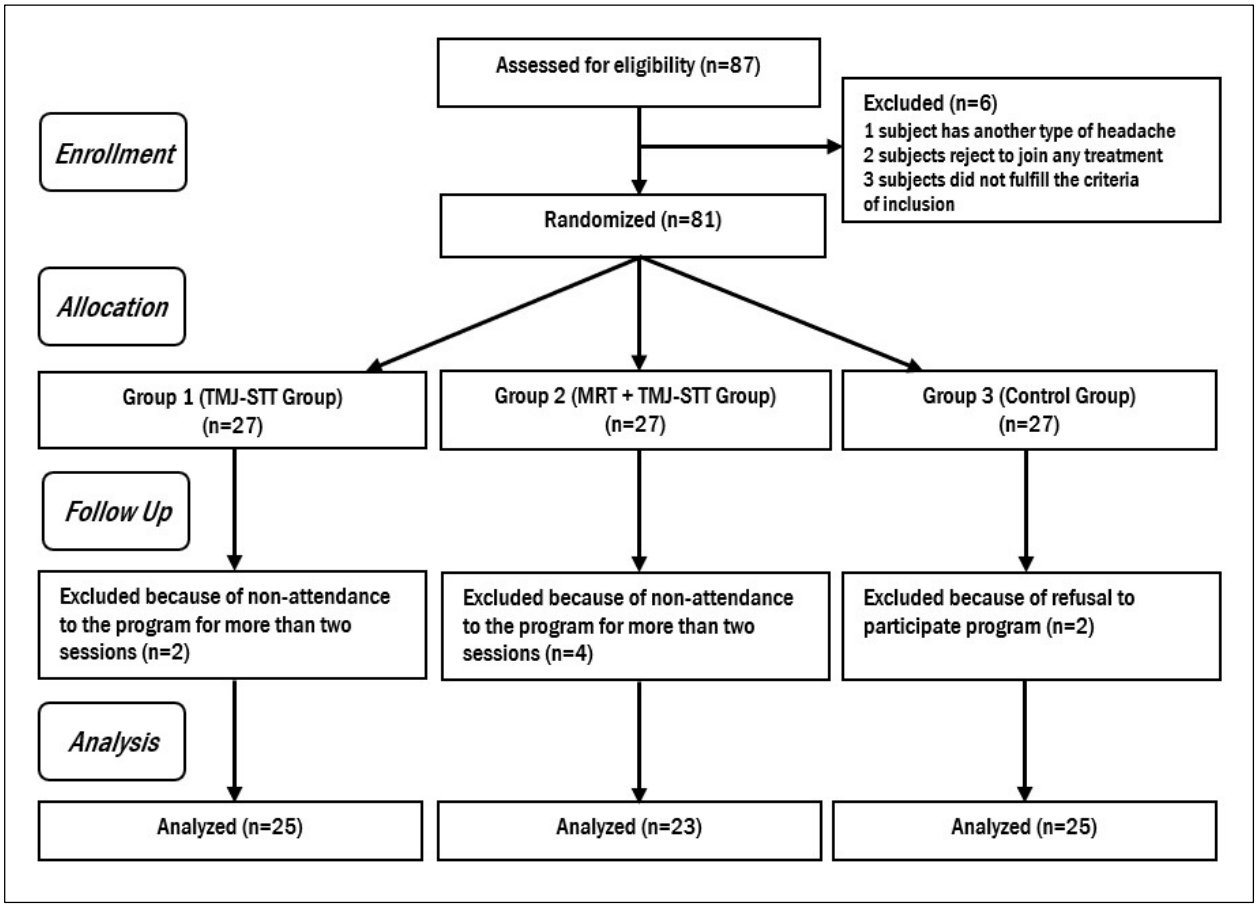


Figure 1. Flowchart according to consort statement for the report of randomized trials.

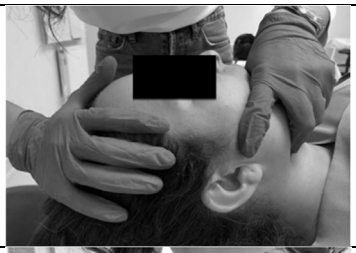
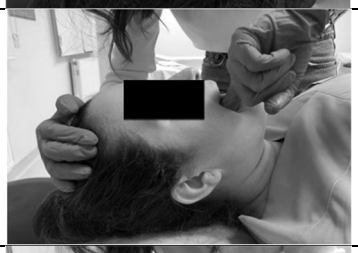
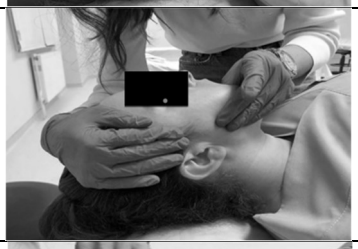
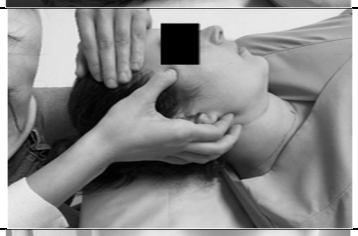
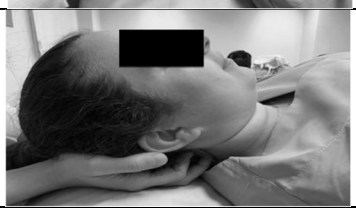
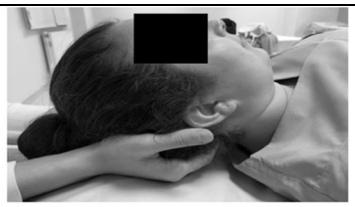
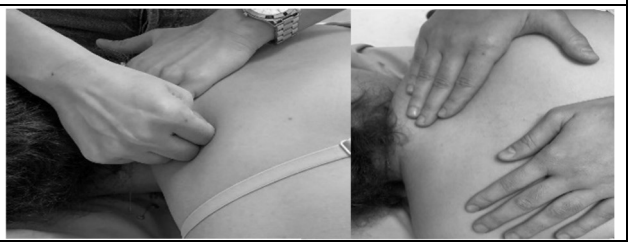
Temporomandibular Joint Soft Tissue Techniques	
Caudal Anterior Glide	
Medial Pterygoid Soft Tissue Mobilization	
M. Masseterius Soft Myofascial Release	
M. Temporalis Soft Myofascial Release	
Mm. Suboccipitalis Myofascial Release	
Soft Tissue Techniques	
Deep Posterior Cervical Fascial Release	
M. Trapezius, M. Levator Scapulae, M. Rhomboideus Myofascial Release	

Figure 2. Manipulative techniques.

assisted mouth opening amount before and after treatment were examined, it was determined that there was a significant increase only in Group 1 ($p<0.05$). No change was observed in Group 2 and Group 3 (Table 2).

When the right and left laterotrusion movements were examined, a significant difference was found between the three groups only after the treatment ($p<0.05$). The right laterotrusion values of Group 1 and Group 2 were significantly higher than the values of Group 3 ($p<0.05$). It was observed that the change in left laterotrusion movement in Group 1 was higher than that in both Group 2 and Group 3 ($p<0.05$). It was determined that right laterotrusion movements significantly increased in both Group 1 and Group 2 after 4 weeks of treatment ($p<0.05$), while there was no change in Group 3 ($p>0.05$) (Table 2).

There was no significant difference among the three groups in terms of cervical flexion, extension, lateral flexion, and rotation angles, both before and after treatment (Table 2). When the changes before treatment and after 4 weeks of treatment were examined, a significant increase was observed in cervical flexion in both Group 1 and Group 2 ($p<0.05$). No change was observed in Group 3. No statistically significant change was observed in any group in terms of cervical extension. A significant increase was found in the right lateral flexion and right rotation angles of Group 1 ($p<0.05$). There was no change in the lateral flexion angles of Group 2 and Group 3 ($p>0.05$). No change was observed in the rotation angles of Group 2 and Group 3 ($p>0.05$) (Table 2).

There was no significant difference among the three groups in Fonseca, HIT-6, BDI, BAI, and SF-36 scores both before and after treatment ($p>0.05$). When the changes before and after treatment were examined, it was observed that there was a statistically significant decrease in Fonseca, HIT-6, BDI, and BAI scores in both Group 1 and Group 2 ($p<0.05$), while no change was observed in any of these scores in Group 3 ($p>0.05$) (Table 3).

When the difference values of the three groups before and after treatment were compared, it was determined that the change in M-MO and right rotation values in Group 1 was significantly higher than in Group 3 ($p<0.05$) (Table 4). It was observed that the change in P-MO, right laterotrusion, and cervical flexion values in Group 2 was significantly higher than in Group 3 ($p<0.05$) (Table 4). The change in Fonseca total, HIT-6 total, BDI total, and BAI total scores in both Group 1 and Group 2 was found to be significantly higher than in Group 3 ($p<0.05$) (Table 4).

DISCUSSION

Our study aims to compare the effects of Temporomandibular Joint (TMJ) relaxation techniques (Group 1), TMJ + Myofascial relaxation techniques (Group 2), and Medical Treatment (Group 3) on cervical joint range of motion, mouth opening, quality of life, Fonseca impact scale, depression, anxiety, and headache in individuals with Tension-Type Headache (TTH). Results showed improvements in quality of life, joint range of motion, headache, depression, and anxiety symptoms in Group 1 and Group 2 compared to Group 3 both before and after treatment. Inter-group analyses demonstrated significant improvements in P-MO, right lateral trusion, and cervical flexion values in Group 2 compared to Group 3. Positive effects were found in M-MO and right rotation values in Group 1 compared to Group 3. Positive changes were observed in Fonseca total value, headache (HIT6), depression (BDI), and anxiety (BAI) values in both Group 1 and Group 2. The data confirm the hypothesis that manipulative-myofascial relaxation techniques positively affect the quality of life, depression, and headache in individuals with TTH. Similarly, De Sousa and De Matos (2014) investigated the impact of myofascial relaxation techniques on cervical range of motion in TTH.[25] They found significant improvement in all cervical movements and reported a significant difference in pre- and post-treatment values.[25,26] On the other hand, Lopez and colleagues (2014) explored the efficacy of two different manual therapy applications. The first group received suboccipital soft tissue inhibition, the second group received occiput-atlas manipulation, the third group received a combination of the two treatments, and the control group received no treatment. They observed an increase in cranioservical flexion in the intervention groups after treatment. They noted greater improvement in occiput-atlas manipulation and suggested that the combination of suboccipital inhibition and occiput-atlas manipulation group

showed better improvement than suboccipital inhibition alone.[27]

In our study, as well as in the mentioned study above, it is observed that soft tissue techniques applied to the suboccipital region are effective. However, in a meta-analysis study investigating the effectiveness of physical therapy methods applied to the suboccipital region in patients with Tension-Type Headache (TTH), six randomized controlled trials were conducted with a total of 505 participants. The Suboccipital Soft Tissue Inhibition Technique (SIT) + Occiput-Atlas-Axis Global Manipulation (OAA) was found to be more effective than SIT in increasing cranioservical extension after 4 weeks of treatment. However, the combination therapy of SIT+OAA may be more effective in the short term (4 weeks), showing no significant difference in the long term (8 weeks).[10] Therefore, the long-term results of our study are needed. In a study conducted by Memmedova to examine the relationship between Temporomandibular Joint Disorder (TMJD) and Tension-Type Headache (TTH) using the Fonseca questionnaire, a higher Fonseca score was reported in individuals with TTH.[28] Looking at the research, it has been observed that headaches and comorbid disorders of TMJD trigger each other.[29] They found that oral problems were more commonly observed in individuals with TTH.[22] In our study, we assessed the presence of TMJD in patients presenting with TTH and the effectiveness of treatments only with the FONSECA questionnaire.[23] According to FONSECA, we do not have information

Table 1. Comparison of features such as bruxism, chewing direction, previous operations, medication use, and cigarette use among the groups.

		Group 1 (N=25)	Group 2 (N=23)	Group 3 (N=25)	
		n (%)	n (%)	n (%)	p
Bruxism history	None	16 (64)	9 (39.13)	14 (56)	0.301 (a)
	Present at night	5 (20)	7 (30.43)	8 (32)	
	Present during the day	1 (4)	5 (21.74)	1 (4)	
	Present both night and day	3 (12)	2 (8.7)	2 (8)	
Chewing direction	Right	6 (24)	4 (17.39)	6 (24)	0.509 (a)
	Left	0 (0)	2 (8.7)	1 (4)	
	Bilateral	19 (76)	17 (73.91)	18 (72)	
Dominant chewing direction	Right	22 (88)	14 (60.87)	19 (76)	0.271 (a)
	Left	2 (8)	7 (30.43)	5 (20)	
	Bilateral	1 (4)	2 (8.7)	1 (4)	
Previous operations	None	22 (88)	19 (82.61)	18 (72)	0.347 (a)
	Present	3 (12)	4 (17.39)	7 (28)	
Medication use	No	14 (56)	13 (56.52)	18 (72)	0.422 (a)
	Yes	11 (44)	10 (43.48)	7 (28)	
Cigarette use	No	18 (72)	18 (78.26)	17 (68)	0.726 (a)
	Yes	7 (28)	5 (21.74)	8 (32)	
Orthodontic treatment history	No	24 (96)	20 (86.96)	23 (92)	0.514 (a)
	Yes	1 (4)	3 (13.04)	2 (8)	
Coexisting diseases	Diabetes	3 (12)	3 (13.04)	2 (8)	0.488 (a)
	Hypertension	- (0)	- (0)	3 (12)	
	Hyperlipidemia	1 (4)	1 (4.35)	1 (4)	
	Other	6 (24)	6 (26.09)	4 (16)	
	None	15 (60)	13 (56.52)	15 (60)	

(a): Chi-Square test.

Table 2. Comparison of maximum mouth opening, active mouth opening, passive opening, laterotrusion right-left, cervical range of motion data' before and after treatment and between groups.

		Group 1	Group 2	Group 3	
		X±SD	X±SD	X±SD	p
Max mouth opening BT		41.08±3.83	37.91±6.63	41.16±4.12	0.052 (b)
Max mouth opening AT		42.60±3.66	39.70±6.67	41.44±3.95	0.126 (c)
	p (BT-AT)	0.003* (e)	0.007* (d)	0.059 (d)	
Active mouth opening BT		34.76±3.43	31.26±6.35	31.76±3.50	0.034* (b)α
Active mouth opening AT		35.72±3.51	33.57±6.54	32.16±3.54	0.021* (b)α
	p (BT-AT)	0.144 (d)	0.017* (d)	0.072 (e)	
Passive mouth opening BT		43.64±3.65	41.61±6.52	43.68±4.28	0.315 (b)
Passive mouth opening AT		44.80±3.56	42.35±6.52	43.88±4.08	0.287 (b)
	p (BT-AT)	0.020* (d)	0.260 (e)	0.140 (e)	
Laterotrusion Right-BT		9.44±2.02	9.17±2.74	8.56±2.36	0.414 (c)
Laterotrusion Right-AT		10.80±2.24	10.52±2.27	8.36±2.41	0.001* (c)α,β
	p (BT-AT)	0.019* (e)	0.028* (d)	0.157 (e)	
Laterotrusion Left- BT		8.88±2.54	8.57±2.57	8.16±2.37	0.595 (c)
Laterotrusion Left- AT		9.76±2.20	9.43±2.02	8.08±2.27	0.009* (b)α
	p (BT-AT)	0.04* (d)	0.191 (d)	0.705 (e)	
Cervical flexion BT		55.2±6.20	51.74±7.01	52.2±8.55	0.243 (b)
Cervical flexion AT		56.2±6.17	53.26±7.48	52.2±8.55	0.203 (b)
	p (BT-AT)	0.025* (e)	0.038* (e)	1.00 (e)	
Cervical extension BT		39.00±6.12	39.35±8.02	39.8±7.57	0.938 (b)
Cervical extension AT		40.20±4.89	40.00±7.39	39.8±7.57	0.978 (b)
	p (BT-AT)	0.107 (e)	0.603 (e)	1.00 (e)	
Right cervical lateral flexion BT		34.2±4.72	36.74±4.67	34.8±6.37	0.197 (b)
Right cervical lateral flexion AT		36.6±4.73	37.39±4.49	34.8±6.37	0.294 (b)
	p (BT-AT)	0.035* (e)	0.579 (e)	1.00 (e)	
Left cervical lateral flexion BT		32.60±4.11	33.26±4.91	33.00±6.12	0.890 (b)
Left cervical lateral flexion AT		33.60±4.45	33.91±4.99	33.00±6.12	0.930 (b)
	p (BT-AT)	0.260 (e)	0.435 (e)	1.00 (e)	
Right rotation BT		47.60±5.02	49.57±5.82	50.00±4.79	0.197 (b)
Right rotation AT		50.20±4.20	50.00±5.64	50.00±4.79	0.981 (b)
	p (BT-AT)	0.038* (e)	0.48 (e)	1.00 (e)	
Left rotation BT		45.40±6.44	45.87±5.36	47.40±5.23	0.427 (b)
Left rotation AT		45.40±5.39	45.87±5.15	46.80±4.97	0.645 (b)
	p (BT-AT)	0.903 (e)	1.00 (e)	0.18 (e)	

*p<0.05. BT: Before treatment. AT: After treatment. (b): Kruskal-Wallis test. (c): One-way ANOVA. (d): t test in dependent groups. (e): Wilcoxon Signed Rank test. α: Significant difference between Group 1 and Group 3. β: Significant difference between Group 2 and Group 3.

about whether TMJD is myogenic or arthralgic. Therefore, we cannot say that every patient with TTH has TMJD. However, based on the literature, it has been indicated that manual therapy methods applied to the cervical region in individuals with TMJD increase mouth opening.[30] Based on this, we believe that the increase in mouth opening measurements in this study is due to the relaxation of the jaw joint and neck muscles caused by the manual techniques applied to TMJ, providing relaxation in TMJ.

There are studies in the literature measuring the effects of Osteopathic Manipulative Therapy (OMTh) and Craniosacral therapies on pain in Tension-Type Headache (TTH). Deodato et al.[11] investigated the effects of osteopathic manipulative therapy

Table 3. Comparison of Fonseca, HIT6, BDS, BAS Parameters before and after treatment and between the groups.

	Group 1	Group 2	Group 3	
	X±SD	X±SD	X±SD	p
Fonseca Questionnaire BT	41.2±20.38	52.83±25.80	44.00±18.20	0.161 (c)
Fonseca Questionnaire AT	32.8±15.55	38.26±24.20	46.60±23.13	0.076 (c)
p (BT-AT)	0.024* (e)	0.001* (e)	0.001* (e)	
The Headache Impact Test-6 (HIT-6) BT	62.48±7.33	63.30±8.75	63.96±7.97	0.840 (b)
The Headache Impact Test-6 (HIT-6) AT	53.92±7.14	51.87±7.94	63.76±9.06	<0.001* (c) α,β
p (BT-AT)	<0.001 (d)	<0.001 (d)	0.892 (d)	
Beck Depression Scale BT	14.84±9.36	14.04±7.92	13.40±10.83	0.742 (b)
Beck Depression Scale AT	9.36±7.63	9.35±8.20	14.68±12.30	0.089 (b)
p (BT-AT)	0.0001* (d)	0.001* (d)	0.195 (d)	
Beck Anxiety Scale BT	19.76±10.87	20.96±13.55	15.12±9.85	0.194 (b)
Beck Anxiety Scale AT	12.20±9.89	12.87±11.24	15.00±11.43	0.592 (b)
p (BT-AT)	0.001* (e)	0.001* (e)	0.917 (d)	
SF-36 General Health Score BT	55.60±20.22	50.87±20.37	57.40±21.37	0.535 (c)
SF-36 General Health Score AT	53.60±17.59	53.04±19.87	56.40±19.01	0.799 (b)
p (BT-AT)	0.482 (d)	0.508 (d)	0.451 (d)	

*p<0.05. BT: Before treatment. AT: After treatment. (b): Kruskal-Wallis test. (c): One-way ANOVA. α: Significant difference between Group 1 and Group 3. β: Significant difference between Group 2 and Group 3. SF-36: The 36-Item Short Form Health Survey.

Table 4. Comparison of the differences (before and after treatment) between the groups.

		Group 1	Group 2	Group 3	
		X±SD	X±SD	X±SD	p
Mouth opening	Maximum	-1.52±2.29	-1.78±2.86	-0.28±0.84	0.02* (b)α
	Active	-0.96±3.18	-2.30±4.28	-0.40±1.08	0.04* (b)β
	Passive	-1.16±2.32	-0.74±3.09	-1.60±7.01	0.313 (b)
Laterotrusion	Right	-1.36±2.51	-1.35±2.74	0.20±0.71	0.008* (b)β
	Left	-0.88±2.03	-0.87±3.09	0.08±0.70	0.072 (b)
Cervical flexion		-1.00±2.04	-1.52±3.17	0.00±0.00	0.049* (b)β
Cervical extension		-1.20±3.62	-0.65±4.60	0.00±0.00	0.343 (b)
Cervical lateral flexion	Right	-2.40±5.42	-0.65±4.84	0.00±0.00	0.126 (b)
	Left	-1.00±4.33	-0.65±4.60	0.00±0.00	0.599 (b)
Cervical rotation	Right	-2.60±5.61	-0.43±2.98	0.00±0.00	0.018* (b)α
	Left	0±6.61	0.00±3.69	0.60±2.20	0.695 (b)
Fonseca Questionnaire		8.40±17.06	14.57±18.02	-2.60±8.55	<0.001 (b)α,β
Headache Impact Test-6 (HIT-6)		8.56±8.66	11.43±10.02	0.20±7.27	<0.001 (c)α,β
Beck Depression Scale (BDS)		5.48±6.29	4.70±5.68	-1.28±4.80	<0.001 (c)α,β
Beck Anxiety Scale (BAS)		7.56±10.48	8.09±9.66	0.12±5.68	0.002* (b)α,β
The 36-Item Short Form Health Survey (SF-36)					
Physical Function		-1.40±10.05	-3.91±19.71	3.00±11.81	0.123 (b)
Physical Role Change		-13.00±38.94	-32.30±38.43	-9.00±38.11	0.053 (b)
Emotional Role Change		-18.68±46.24	-28.98±40.59	-2.66±44.01	0.056 (b)
Energy		-7.40±20.62	-11.52±18.12	-0.40±19.89	0.145 (c)
Mental Health		-5.28±20.16	-9.22±15.51	-6.56±20.42	0.47 (b)
Social Functioning		-42.50±16.44	-11.96±21.15	0.50±16.72	0.167 (b)
Pain		-12.80±23.21	-19.78±20.43	-6.90±18.52	0.063 (b)
General Health Perception		2.00±13.99	-2.17±15.51	1.00±17.91	0.295 (b)

*p<0.05. α: Significant difference between Group 1 and Group 3. β: Significant difference between Group 2 and Group 3.

on chronic tension-type headache and forward head posture They included 10 individuals in the OMTh group and 10 individuals in the control group. As a result, they found that OMTh was effective in terms of both pain duration, intensity, and head posture.[11] In a systematic review and meta-analysis study investigating the effects of craniosacral therapies on headaches, 735 studies were examined, and ultimately, four studies were included. The study suggests that craniosacral therapy has clinically insignificant effects on pain intensity but does not observe any significant effects on disability or headache outcomes.[31] A study examining the effects of TMJ and cervical region treatment on pain and functional improvement in individuals with TTH has been found in the literature. They found that both TMJ and cervical region treatment groups showed a significant decrease in HIT6 scores before and after treatment.[32] Choi et al.[18] investigated the effects of temporomandibular disorder treatment on headache and quality of life in individuals with TTH. The study reported that the group treated with TMJ+cervical manual therapy showed more reduction in HIT6 scores compared to the cervical manual therapy and conservative treatment group. The application of cervical manual therapy along with temporomandibular joint treatment to individuals with TTH resulted in a decrease in pain frequency and intensity, along with an increase in quality of life.[18] In this study, parallel to the literature, although no significant difference was observed in SF-36 values between groups, improvement was observed in all parameters in both groups undergoing manual therapy in intra-group evaluations.[26,33] We believe that this is the most important factor in increasing the quality of life, especially with the reduction of headaches. In a study conducted with military firefighters, a painful TMJD was found to be associated with daytime bruxism and anxiety. They also indicated that painless TMJDs are a risk factor for the development of anxiety and daytime bruxism tension-type headaches.[34] Manual therapy (suboccipital soft tissue techniques and articular techniques) was investigated for its effect on anxiety and depression in individuals diagnosed with TTH aged 18-65. They stated that manual therapy techniques reduced depression and anxiety symptoms.[26]

In conclusion, the study supports that TMJ release and myofascial release techniques are effective interventions in improving the quality of life, reducing depression and anxiety, and relieving headaches in individuals with TTH. The difference between our study and the literature is that TMJ applications are being tested for the first time in individuals diagnosed with TTH.

Limitations

Despite providing valuable date there are several limitations that sould be pointed. First, the treatment program is relatively short aslittle as 4 weeks. Second, since it is difficult to reach the patient due to the pandemic and the patients, it was challenging to include patients for the active participation. Third, both evaluation and treatment were applied by the same physiotherapist which could lead to a potential bias. Future studies evaluating long-term results with larger sample sizes are emergently needed and.

Conclusion

In conclusion, we think that both TMJ and MRT applications are effective in the treatment of TTH while MRT techniques and TMJ techniques in combined with appropriate exercise regimens could be performed for individuals with TTH who are under the conventional pain treatment.

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ORIGINAL ARTICLE

Pediatric Bobath Concept in management of children with cerebral palsy: view of Turkish Bobath therapists

Serebral palsili çocukların tedavisinde Pediatrik Bobath Konsepti: Türk Bobath terapistlerinin görüşü

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Abstract

Purpose: Pediatric Bobath Concept (PBC) is a family-child centered holistic concept applied interdisciplinary to support the functional skills of children with cerebral palsy. The aim of this study was to examine the effects of PBC on children, parents, and themselves from the perspective of Bobath therapists in Turkey.

Methods: In this observational study, 104 (69.2% female) Bobath therapists with a mean age of 37.9+6.1 years participated. The Pediatric-Bobath Impact Questionnaire (P-BIQ) was developed by the Delphi method. Content validity (Lawshe's Content Validity Index-CVI) and test-retest reliability (Intraclass correlation coefficient -ICC) were examined. The relationships between the rates of change in children, parents, and therapists were analyzed using the Chi Square ($\chi 2$) test and the effect sizes of the relationships were analyzed according to Cramer's V values.

Results: According to the P-BIQ (CVI=0.836, ICC >0.737), at least 74% of therapists reported that the PBC positively affected children (compliance with therapy and home program, body structure and function, activity and participation, environmental adaptations), parents (compliance with therapy and home program) and themselves (sense of professional competence and motivation). Compliance of the child, parent, and therapist was positively associated with the child's activity and participation levels and environmental adaptation ($p<0.001$, Cramer's V>0.20).

Conclusion: PBC contributes to the development of children as well as to parental compliance, and to the therapist's training and sense of professional competence. Increased compliance of children, parents, and therapists supports the child's functional development, social participation, and adaptation to the environment.

Keywords: Cerebral palsy, Child, Validation study.

Öz

Amaç: *Pediatrik Bobath Konsepti (PBK), serebral palsi ve benzeri nörogelişimsel probleme sahip çocukların fonksiyonel becerilerini desteklemek amacıyla transdisipliner uygulanan aile-çocuk merkezli holistik bir konsepttir. Bu çalışmanın amacı, Türkiye'deki Bobath terapistlerinin bakış açısından PBK'nin çocuklara, ebeveynlere ve kendilerine etkilerini incelemekti.*

Yöntem: *Bu gözlemsel çalışmaya yaş ortalaması 37.9+6.1 yıl olan 104 (%69.2 kadın) Bobath terapisti katıldı. Delphi yöntemi ile Pediatrik-Bobath Etki Anketi (P-BIQ) geliştirildi. İçerik geçerliliği (Lawshe's İçerik Geçerlik İndeksi-CVI) ve test-tekrar test güvenilirliği (Sınıfiçi Korelasyon Katsayısı-ICC) incelendi. Çocuklar, ebeveynler ve terapistlerdeki değişim oranları arasındaki ilişkiler Ki Kare ($\chi 2$) testi kullanılarak analiz edildi ve ilişkilerin etki büyüklükleri Cramer's V değerlerine göre incelendi.*

Bulgular: *P-BIQ anketine (CVI=0.836, ICC>0.737) göre terapistlerin en az %74'ü PBK'nin çocukları (terapi ve ev programına uyum/motivasyon, vücut yapı ve fonksiyonları, aktivite ve katılımları, çevresel düzenlemeler), ebeveynleri (terapi ve ev programına uyum/motivasyon) ve kendilerini (mesleki yeterlilik hissi ve motivasyon) olumlu etkilediğini belirtti. Çocuk, ebeveyn ve terapistin uyumu/motivasyonu çocuğun aktivite, katılım düzeyleri ve çevresel düzenlemeler ile pozitif ilişkiliydi ($p<0.001$, Cramer's V>0.20).*

Sonuç: Çocukların gelişimine olduğu kadar PBK, ebeveynlerin uyumuna ve terapistin eğitimine ve mesleki yeterlilik duygusuna da katkıda bulunur. Çocukların, ebeveynlerin ve terapistlerin artan uyumu, çocuğun işlevsel gelişimini, sosyal katılımını ve çevreye uyumunu destekler.

Anahtar kelimeler: *Serebral palsi, Çocuk, Geçerlik çalışması.*

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INTRODUCTION

Cerebral palsy (CP) is a group of permanent movement and posture disorders resulting from damage to the developing brain that is not progressive but causes activity and participation limitations.[1] Motor disorders are often accompanied by sensory, perception, cognition, communication, and behavioral disorders, epilepsy, and secondary musculoskeletal problems, and these comorbidities may persist throughout life.1,2 Rehabilitative practices are central to the treatment of children with CP. The Pediatric Bobath Concept (PBC) was developed by Dr. Karel and physiotherapist Berta Bobath. Today, it is a child- and parent-based concept that includes the International Classification of Functioning, Disability and Health (ICF) framework, which is widely used by physiotherapists, occupational therapists, and speech-language pathologists in the rehabilitation of children with CP and similar neurodevelopmental problems.[2]

The PBC is a transdisciplinary (physiotherapist, occupational therapist, speech-language pathologist) approach that includes a holistic assessment to support gross motor, fine motor, eating-swallowing, and visual functions, which affect the independence of children with neurodevelopmental problems, to decide on adaptive devices and orthoses, and to refer the patients to other medical approaches. The current PBC includes targeted activity-oriented therapeutic interventions that are individualized for the child. The therapist works to improve the child's motor function and postural control by regulating muscle tone and facilitation of automatic and voluntary movements for the target activity.[2,3] Multiple repetition of the target activity is ensured by facilitation of normal movement with different sensory-motor and perceptual stimuli, not only during therapy but also in different environments. In all applications within the concept, the therapy continues dynamically, considering the active participation and motivation of the child and family. Today, the applications of the PBC are shaped under the title of "application with clinical reasoning".[2-4]

The parent is an important team member of the PBC.[3,4] The parent plays a key role in bringing the therapy into daily life and the home program. The therapist focuses on problem solving by analytically and predictively examining the child's movements during assessment and observation, and engages in a collaborative interaction with the child and parent throughout the intervention. First, "what the child can do" and "how the child can do it", then "what the child cannot do" and "why the child cannot do it" are assessed. After the assessment, the parent contributes to the identification of target activities. The parent ensures that these target activities are repeated in different environments (home, school, and social settings) and that child-specific assistive devices and adaptive equipment appropriate to the biomechanics of normal movement are provided to support the target activity. They participate in the adaptation of the environment and the child to each other during the target activities.[3,4]

The concept examines the dynamic interaction of body structures and disorders, activity and participation levels, and personal and environmental factors in CP and similar neurodevelopmental problems from a “systems science perspective”.[2,4] According to the PBC, the realization of target activities can be possible by changing many linear and non-linear systems.[2] Many factors can influence the development of the target activity, ranging from the child's level of exposure to their access to the therapy. It is therefore very difficult to generate scientific evidence.[2,4] In the last few years, many professionals in the world of childhood disability management have emphasized the need for research to demonstrate the impact of the PBC.[5,6] The reason for this is that in the past some practitioners focused on hands-on practices rather than activities and participation, and some practitioners developed different aspects of the PBC and developed various offshoot-approaches under other names.[7,8]

The prevalence of CP is above the world average in Turkey (4.4./1000).[9] In Turkey, the PBC is widely applied for the intervention of CP and similar neurodevelopmental problems. The concept provides comprehensive clinical theoretical and practical training for physiotherapists, occupational therapists, and speech-language pathologists in the lifelong rehabilitation of children. The European Bobath

Tutors Association (EBTA) has set a minimum of 240 hours for therapists for basic training in the PBC.10 After basic training, different durations have been set for advanced courses. There are more than 300 EBTA-approved Pediatric Bobath therapists in Turkey, including four senior Bobath Tutors. The majority of therapists in Turkey are physiotherapists.[10] Many studies and dissertations have been conducted on the concept. Despite its widespread application in Turkey, there is no study evaluating the effects of the PBC on children, parents, and therapists from an ICF perspective.

Evidence-based practices are needed to demonstrate the widespread impact of the Bobath approach.[2-8] Evidence-based practices can be possible with evaluation methods appropriate to the nature of the concept. The aim of this study was to examine the effects of the PBC on the child, parents, and therapist from the therapist's perspective within the framework of ICF. Our hypotheses were: 1) The PBC affects the child's compliance with therapy and home program, functions, activity, and participation levels, and determination of environmental arrangements, 2) The PBC affects the parental compliance with therapy and home program, 3) The PBC affects the therapist's sense of professional competence and motivation, 4) Changes in the child's, parent's, and therapist's personal characteristics (sense of competence, compliance) are associated with changes in the child's functioning, activity, participation level, and environmental arrangements.

METHODS

This is a prospective cross-sectional study. Ethics committee approval for the study was obtained from Hacettepe University, Non-Interventional Clinical Ethics Committee (2022/01-48, Date: 04.01.2022). The study was conducted at Hacettepe University, Faculty of Phsical Therapy and Rehabilitation, Cerebral Palsy and Pediatric Rehabilitation Unit.

Participants

The population of the study was Bobath therapists who were members of the Bobath Therapists Association (BTA). The inclusion criteria were: voluntarily agreeing to participate in the study, having completed at least 8 weeks (240 hours) of EBTA-approved Basic Pediatric Bobath Concept training, having received the title of Bobath Therapist, and having at least one year of PBC experience, and working in Turkey. Therapists who answered the survey questions incompletely were excluded from the study. In addition to the ethics committee approval, permission was obtained from the BTA to reach its members.

Assessment

A web-based questionnaire was used in the study. The questionnaire consisted of two parts. In the first part, the characteristics of the participants such as gender, age, occupation, type of institution, and duration of employment were questioned. In the second part, the Pediatric Bobath Impact Questionnaire (P-BIO) was questioned.

P-BIO was created to assess the impact of PBC on the characteristics of children, parents, and therapists from the perspective of therapists. Under the leadership of a specialist pediatric physiotherapist with 35 years of experience (Bobath Tutor certificated by EBTA), 6 pediatric Bobath physiotherapists with at least 5 years of experience developed the questionnaire according to the Delphi method by making video conferences with a focus group at four different times.[11]

In the first round, the target group (therapists), what to measure (Bobath's impact from therapists' perspective), and how to measure it (Likert-type questionnaire) were decided. Since the core team of the Bobath approach is the child, the parent, and the therapists, the impact of the intervention can only be predicted by these people. During these interviews, it was decided to first develop a questionnaire for therapists, considering the ICF sub-dimensions, family, and child-based approach in order to be up-to-date. Considering the ICF sub-dimensions of the questionnaire (body structure and functions, activity, participation, and personal and environmental factors), team members (therapist, parent, and child), the items were prepared about how PBC practices affect these dimensions. In the second round, all question items were combined to form a question pool. Similar or redundant items were removed. The content validity of the items deemed "necessary and appropriate" for the questionnaire among the candidate items was

calculated according to Lawshe's Content Validity Index (CVI). CVI>0.62 was found to be appropriate in terms of content validity.[12] Items below this value were removed. At the third meeting, expert opinions were combined to create a survey of 11 items including child (7 items), parents (2 items), and therapists (2 items). A Likert-type survey with options as "decreased" "no change", and "increased" was selected to have two-way answers and not to put psychological pressure on therapists when answering. The final CVI value of the questionnaire was 0.83. In the fourth meeting, the comprehensibility of the questionnaire through the draft version was asked to the focus group (Fourteen Bobath therapists). After revisions, the final version of the standardized form of the questionnaire was prepared by two physiotherapists using a web-based form. Two additional questions were asked: 1) the effect of the PBC on the therapist's general clinical knowledge, assessment, and therapy process for children with CP, and 2) the effect of the principles of the PBC on infants, children, and adolescents.

The questionnaires were delivered to the therapists via a web-based link. Informed consent was obtained from the participants with the informed consent form included in the questionnaire sent to the therapists. Therapists were asked to answer the questions in the questionnaire completely.

Statistical analysis

The Statistical Package for Social Sciences (IBM Corp., Armonk, NY, USA, 2019) version 26.0 were used. The compatibility of the data distribution was reviewed visually (probability plots and histograms) and through analytical methods (Kolmogorov–Smirnov/Shapiro–Wilk's test). Continuous variables are presented with mean ± standard deviation (SD). Categorical variables are summarized as frequencies and percentages.

According to item number of the P-BIO, at least 55 children were planned to be included in the study since the sample size should be at least 5-10 times the number of questions. For test-retest reliability, at least one-fifth of the participants re-took the test. ICC values were analyzed for test-retest reliability. ICC values are defined as follows: < 0.5, poor; between 0.5 and 0.75, moderate; between 0.75 and 0.9, good; and > 0.9 excellent reliability.[13]

Chi-squared tests were used to examine the associations between the child's, parent's and therapist's compliance with therapy after the PBC and children's functioning, activity and participation levels, and changes in environmental factors. The effect size in the relationships was analyzed with Cramer's V values. Cramer's V coefficient was calculated to measure the effect size in a cross-tabulated table: a calculated effect size for cross-tables and interpreted as 0.5: large effect (or relation), 0.3: medium effect, and 0.1: small effect.[14] A p-value less than 0.05 was accepted as statistically significant.

RESULTS

One hundred and sixty-five Bobath therapists were invited to the study. Twenty-five of them were excluded because they did not accept the study and 36 of them were excluded because their data were incomplete. One hundred and four Bobath therapists completed the study, and the mean age was 37.89+6.11 years (27-55 years), 72 (69.2%) of the participants were female, and 32 (30.8%) were male. Most of the participants (40%) were working in special education and rehabilitation centers. According to their educational status, 18% had a master's degree and 23.8% had a doctorate degree. More than half of the therapists were Bobath therapists for at least six years. Working hours were most often ranged between 5-7 days a week, 4-9 hours a day (Table 1).

The test-retest reliability values of the items of the P-BIO questionnaire were between 0.737 and 0.910. The highest reliability was "change in compliance with the home program". The lowest reliability was "change in activities of daily living" (Table 2).

According to the P-BIO questionnaire: Ninety-four percent of the therapists reported positive improvements in children's body structure and function after the PBC, 74% reported an increase in children's activity, 81% reported an increase in children's social participation, and 75% reported an increase in the identification of environmental factors.

Eighty-two percent of the therapists reported that after the PBC, parental compliance with therapy increased and 75%

reported that parental compliance with home program increased.

After becoming a pediatric Bobath therapist, 82% of therapists reported increased professional motivation and 83% of therapists reported an increased sense of professional competence (Table 3).

According to the therapists, the PBC contributed greatly to the general clinical knowledge, assessment, and every stage of the treatment process in CP (Figure 1). The three topics that the PBC contributed the most within the framework of general physiotherapy and rehabilitation clinical knowledge were muscle tone and regulation (85.7%), typical-atypical development in children (84.8%), and holistic view of the child (84.7%). The three subjects it contributed the most during the evaluation process were observation (92.4%), individual goal selection (86.6%), and clinical problem solving (82.9%) skills. Its contribution to the therapy process was listed as facilitation of normal movement and reactions (85.8%), activity-based individualized program (79.1%), and family education (74.3%) (Figure 1).

According to Bobath therapists: Among the principles of the PBC, parental education and home program were most effective in infants with CP (66.9%), the principles of recommending adaptive devices (orthotics, walking aids, and necessary additional interventions) were most effective in children with CP (52.8%), and the principles of managing secondary problems (contracture, pain and loss of muscle strength) and supporting social participation were most effective in adolescents with CP (50.4%) (Figure 2).

According to the responses to the P-BIO questionnaire, therapists' motivation and sense of professional competence, and family compliance and motivation were positively associated with positive improvements in children's functioning, activity, and participation levels, and environmental modifications. In particular, an increase in parental compliance with therapy had a large effect size on the child's activities of daily living and social participation, while family compliance with the home program had a large effect size on the child's functional development ($p<0.05$, Cramer's $V>0.20$, Table 4).

Table 1. Characteristics of the participants.

	Mean±SD
Age (year)	37.9±6.1
	n (%)
Gender	
Female	72 (69.2)
Male	32 (30.8)
Education level	
License	25 (24.0)
Master's degree	60 (57.7)
Doctorate degree	19 (18.3)
Bobath therapist (year)	
1 to 3	20 (19.2)
4 to 6	30 (28.8)
7 to10	34 (32.7)
>10	20 (19.2)
Organization type	
Public hospital	8 (7.7)
Special education center	40 (38.5)
Private hospital	5 (4.8)
University	25 (24.0)
Counseling center	26 (25.0)
Working day	
1-2	2 (1.9)
3-4	12 (11.5)
5-7	90 (86.5)
Working hours	
1-3	6 (5.8)
4-6	24 (23.1)
7-9	71 (68.3)
10-12	3 (2.9)

Table 2. Test-retest reliability values of the Pediatric-Bobath Impact Questionnaire (P-BIQ) items.

P-BIQ items	ICC	95% CI
Item 1	0.766	0.560-0.904
Item 2	0.855	0.673-0.940
Item 3	0.737	0.547-0.887
Item 4	0.855	0.673-0.940
Item 5	0.876	0.707-0.950
Item6	0.878	0.721-0.950
Item 7	0.863	0.690-0.943
Item 8	0.878	0.721-0.950
Item 9	0.863	0.690-0.943
Item 10	0.910	0.788-0.963
Item 11	0.870	0.702-0.946

ICC; intra-class correlation coefficient (Two-way mixed effects model (2,1) for absolute agreement with a 95% confidence interval).
CI: Confidence interval.

DISCUSSION

Although it is a widely used therapeutic intervention in Turkey for infants at high risk of CP, children diagnosed with CP, and children with similar neurodevelopmental problems, there exists no report examining the collaborative effect of the PBC. In this study, for the first time in Turkey, the effects of the PBC on children, parents, and therapists are examined from the therapist's perspective under the ICF framework. A valid and reliable subject-specific P-BIO questionnaire was developed. According to the Bobath therapists, the PBC is useful in improving the function, activity, and participation level of the child with CP and identifying their environmental needs. After the PBC, the increase in the child's, parent's, and therapist's motivation and adherence to the therapy program, the increase in the therapist's sense of professional competence, and the increase in the child's functioning, activities, and level of participation have positive effects. The PBC is also effective in training therapists. It is especially useful in terms of education in children with CP in terms of muscle tone and regulation, observational assessment, individual goal setting, and facilitation of typical movements and reactions during functional activity. According to the Bobath therapists, among the principles of the PBC, the principles of family education and home program were most important in infancy, the principles of

Table 3. Percentage distribution of responses to the Pediatric-Bobath Impact Questionnaire (P-BIQ) items.

After the Pediatric Bobath Concept	Decreased n (%)	No change n (%)	Increased n (%)
Child			
How did the body structure of the children you treated change?	0 (0)	6 (6)	98 (94)
Tonus problems			
Pain			
Fatigue			
How did the physical functioning of the children you treated change?	0 (0)	6 (6)	98 (94)
Range of motion of the joint			
Selective movements			
Body stabilization			
Postural control			
How have activities of daily living changed?	1 (1)	26 (25)	77 (74)
Sitting, walking, transferring, going up and down stairs			
Nutrition			
Personal care			
The Game			
How has participation changed?	0 (0)	20 (19)	84 (81)
Daily life routines			
Social activities			
How has the child's environment changed?	1 (1)	25 (24)	78 (75)
Domestic modifications			
Modifications in social environments			
Orthotics and assistive device support			
How did the compliance of the children you took into therapy change?			
How has the compliance of the children in your therapy changed with the home program?	1 (1)	8 (13)	95 (86)
Parent	1 (1)	8 (13)	95 (86)
How did his/her compliance with therapy change?	2 (2)	22 (18)	80 (82)
How did his/her compliance with the home program change?	1 (1)	25 (24)	78 (75)
Therapist			
How was your professional motivation affected?	13 (12)	6 (6)	85 (82)
How has your sense of professional competence been affected?	1 (1)	17 (16)	86 (83)

Table 4. Associations between changes in therapist, child and parent after the PBC and children's functioning, activities of daily living, social life and environmental regulation.

	Functions			Activities of daily living		
	Increased (n)	No change (n)	Decreased (n)	Increased (n)	No change (n)	Decreased (n)
Compliance and motivation of the child						
Increased	92	3	0	73	22	0
No change	5	3	0	3	4	1
Decreased	1	0	0	1	0	0
p/ Cramer's V		0.001/0.393			0.003/0.277	
Parental compliance with therapy						
Increased	79	1	0	68	12	0
No change	18	4	0	9	13	0
Decreased	1	1	0	0	1	1
p/ Cramer's V		<0.001/0.398			<0.001/0.584	
Parental compliance with the home program						
Increased	78	0	0	69	9	0
No change	20	5	0	8	16	1
Decreased	0	1	0	0	1	0
p/ Cramer's V		<0.001/0.541			<0.001/0.411	
Professional motivation of the therapist						
Increased	81	4	0	65	20	0
No change	4	2	0	2	4	0
Decreased	13	0	0	10	2	1
p/ Cramer's V		0.009/0.300			0.010/0.251	
Therapist's sense of professional competence						
Increased	84	2	0	70	16	0
No change	13	4	0	7	10	0
Decreased	1	0	0	0	0	1
p/ Cramer's V		0.003/0.337			<0.001/0.748	

Cramer's V, 0.5: large effect, 0.3: medium effect and 0.1: small effect.

management of assistive devices used to support target activities were most important in childhood-adolescence, and the principles of prevention of secondary problems and promotion of social participation were most important in adulthood.

The PBC provides therapists with a training model that includes general clinical knowledge and assessment and treatment principles specific to children with CP.[2-4] It's a child- and parent-centered living concept based on theoretical scientific knowledge about typical/atypical movement development.[2-4] In recent systematic reviews examining the impact of the PBC, it has been stated that it is a passive practice according to experimental studies with insufficient level of evidence.[5-6] On the other hand, the importance of empirical evidence for interventions is undeniable, but scientific knowledge is also a major factor in the basis and shape of an intervention. Reasons ranging from brain involvement to living conditions may affect the effectiveness of intervention in CP rehabilitation differently for each child.[15] It is therefore also difficult to establish evidence for the concept. The PBC is an approach that includes many therapeutic aspects rather than an intervention. In light of its holistic approach, it supports the neurodevelopmental processes of the child, while providing parents/caregivers with home programs and education, and physiotherapists with both educational and clinical practice skills.[2-4] Therefore, it is necessary to investigate the effects on the parent/caregiver and therapist as well as on the functioning of children with CP. In this study, according to the P-BIO questionnaire, the PBC was shown to have effects on the functional skills of children as well as on parents and therapists.

Table 4. *Continued.*

	Social inclusion			Environmental adaptations		
	Increased (n)	No change (n)	Decreased (n)	Increased (n)	No change (n)	Decreased (n)
Compliance and motivation of the child						
Increased	79	16	0	74	20	1
No change	4	4	0	3	5	0
Decreased	1	0	0	1	0	0
p/ Cramer's V		0.065/0.229			0.121/0.187	
Parental compliance with therapy						
Increased	73	7	0	68	12	0
No change	11	11	0	10	12	0
Decreased	0	2	0	0	1	1
p/ Cramer's V		<0.001/0.514			<0.001/0.571	
Parental compliance with the home program						
Increased	70	8	0	78	0	0
No change	14	11	0	0	25	1
Decreased	0	1	0	0	0	0
p/ Cramer's V		<0.001/0.417			<0.001/1.0	
Professional motivation of the therapist						
Increased	73	12	0	67	17	1
No change	1	5	0	2	4	0
Decreased	10	3	0	9	4	0
p/ Cramer's V		<0.001/0.409			0.126/0.186	
Therapist's sense of professional competence						
Increased	74	12	0	70	15	1
No change	10	7	0	8	9	0
Decreased	0	1	0	0	1	0
p/ Cramer's V		0.004/0.325			0.011/0.251	

Cramer's V, 0.5: large effect, 0.3: medium effect and 0.1: small effect.

Providing evidence on a topic is possible through qualitative or quantitative evaluation methods. Methodologically, specific questionnaires can be developed on a topic by taking the attitudes and opinions of experts. The primary validity to be considered in questionnaire development is the content validity of the measurement tool. Content validity determines the extent to which each item covers the trait intended to be measured.[16,17] In previous studies, no comprehensive specific questionnaire evaluating the effect of the PBC was found. First of all, in order to be methodologically strong in this study, the P-BIO questionnaire was created by taking expert opinion with the Delphi method.[18] The question items selected to show the effect of the PBC had high content validity based on expert opinions. A questionnaire should have temporal stability as well as validity. Temporal stability is determined by test-retest reliability. Test-retest reliability refers to the consistency of results when the same test is repeated on the same sample at a different time point. For test-retest reliability, a sufficient period of time should elapse so that the participant does not change their mind but also forgets their answers to the questionnaire. An average period of 2-4 weeks is methodologically recommended.[19] In our study, the questionnaire was sent to the therapists at two-week intervals and the temporal stability of the P-BIO questionnaire was found to be adequate by the therapists.

Maintaining a stable posture during functional activities requires a complex interaction between the musculoskeletal and the nervous system. Head-trunk stabilization (i.e. axial segment stabilization) is the primary reference frame for postural control.[20] During the PBC, postural reactions and head-trunk stabilization are facilitated for typical functional

movement development. Akbaş et al.[21] showed that "Bobath-based trunk training" applied for eight weeks, 2 days a week for 45 minutes increased trunk extensor muscle activation in children with CP. Arı et al.[22] stated that "Bobath-based trunk control training" applied for 6 weeks, 2 days a week, 45 minutes a day increased trunk muscle strength in children with CP. Türker et al.[23] found that "Bobath-based goal directed therapy" applied for 12 weeks, 3 days a week in children with CP increased functional independence and quality of life of children in daily life. Acar et al.[24] emphasized that Bobath-based neck and trunk control (45 min.2 g/12 hf) exercises were effective on feeding and swallowing functions of children with CP. In this study, according to three-quarters of the therapists who have been applying the PBC for at least one-year, neurodevelopmental therapy contributed positively to body structure and function, activity, and participation levels of children during this period. In conclusion, individualized goal-oriented and activity-focused PBC for children with CP is beneficial for both function and activity and participation levels.

CP is a chronic neurodevelopmental disorder that requires lifelong therapeutic exercise habits. The acquisition of this habit can be achieved through personal compliance and motivation.[25] Motivation also supports the learning of a functional skill. Furthermore, as the motivation of the child and the parents increases, the sustainability of the intervention increases.[25,26] In this study, it was found that the increase in the compliance and harmony of the therapist, family, and child after the PBC positively affected the increase in the child's functioning, activities of daily living, social participation, and environmental regulation. In this study, when the age groups were examined separately according to the therapists, the importance of family education and home program management in infancy, management of adaptive devices in childhood, and management of secondary problems and social participation in adolescence were emphasized. We can say that the PBC is a living concept that responds to all habilitative and rehabilitative needs of individuals with CP from infancy to adulthood. We can also say that the harmony and motivation of team members in the PBC will support the functional development of the individual.

Parents are in the center of pediatric rehabilitation. Evan-Rogers et al.[27] investigated the experience of parents after short-term and intensive PBC and emphasized that parents found the PBC by experienced therapists to be beneficial and supportive for their children's functional development. In addition, according to the parents, in the PBC, the therapists' setting of collaborative goals with the child and parents is motivating.[27] In this study, according to most of the therapists, parents' and children's motivation and compliance with the home program increased after the PBC. In the concept, parents are given responsibility for the home program process. It can be said that the reason for the increase in compliance and motivation of the parents is that they feel responsibility as a team member and the instinct to own the process.

In a study conducted in Spain, the Bobath experiences of a group of Bobath therapists working with children with CP were questioned. As a result of a thematic analysis, the core features of the Bobath concept were identified as 1) normal movement, 2) global concept, 3) observation, 4) the centrality of tone, 5) working with families. Additional principles were identified as including assessment and therapy, applying motor learning principles, and transferring treatment into function. Therapists reported that they no longer adhere to the theoretical perspective of pathological reflexes and reflex/tone inhibition.4 In Brazil, it was reported that most of the good therapeutic work is carried out by Bobath therapists. In Brazil, Bobath therapy uses the child's own active self-movement, participation in therapeutic planning, and family involvement.7 The situation is similar in Turkey. This study is the first cross-sectional study on Bobath therapists in Turkey and it is seen that two out of every five people have postgraduate education and most of them have knowledge about the research design. We can say that most of the therapists who are interested in PBC are also the ones who follow the current literature. In this study, it was stated that the PBC contributed to the therapists mostly in tone knowledge, atypical-typical motor development knowledge, observation, clinical problem solving, individualized goal setting, and facilitation of typical movements during activity. In addition,

most Bobath therapists have reported that their sense of professional competence was positively affected after the PBC training. The concept provides a framework intended to be applied in clinical practice, education, and research for Bobath therapists.

Limitations

This study has several limitations. The PBC is applied by physiotherapists, speech-language pathologists, and occupational therapists. In Turkey, the number of Bobath therapists in the field of occupational therapists and speech-language pathologists is quite small. A limitation of the study is that the expert committee and focus group that developed the P-BIO questionnaire consisted only of physiotherapists. Another limitation is that although we have reached a large number of Bobath therapists, a high number of participants gave incomplete answers. The questionnaire was prepared to be administered over the phone for the convenience of the respondents. It is thought that there are deficiencies in the data due to the system shutting down while switching between questions and difficulties in marking matrixed answers by touching the small phone screen.

Conclusion

According to Bobath therapists, the PBC is a comprehensive intervention that contributes to all aspects of the child's development, especially physical development, as well as to the compliance/motivation of the parents and the therapist's education, sense of professional competence and compliance with therapy. Increased compliance and motivation of the child, parents and therapist supports the child's functional development, social participation and adaptation of the environment to the child. The PBC is continuously updated in the light of the neurodevelopmental and neurophysiological theoretical knowledge on which it is based, and is developed after regular meetings, congresses, and workshops within the professional organizations formed by educators. Setting individual measurable goals, activity and participation-oriented perspective, orthotic and adaptive device recommendations to support activity, and in-home modifications are within the scope of the concept. We think that the P-BIO questionnaire, which was developed specifically for this study, is a questionnaire that can be used to evaluate the effect of the PBC on the therapist, the child, and the parent from the ICF perspective. In order to be complementary, we are planning to develop versions that examine parents' and children's perspectives. It is thought that evaluating other psychometric properties of the P-BIO in future studies will support the usability of the questionnaire.

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ORIGINAL ARTICLE

Kanser tanılı çocuklarla normal gelişen çocukların tek ve çift görev yürüyüş parametrelerinin karşılaştırılması

Comparison of single-and dual-task gait parameters of children with cancer and typically developing children

Emel TAŞVURAN HORATA[1], Hamide NUR ÇEVİK ÖZDEMIR[2], Yunus Emre KUNDAKCI[1], İbrahim EKER[4]

Öz

Amaç: Bu çalışma, kanser tanılı çocuklar ile normal gelişen çocuklar arasındaki tek ve çift görev yürüme parametrelerini karşılaştırmayı amaçladı.

Yöntem: Tek ve çift görev koşulları altında 10 metre yürüme testi ile değerlendirilen yürüme parametreleri (yürüyüş hızı, kadans ve çift adım uzunluğu) ve çift görev maliyeti hesaplandı. Karşılaştırmalarda t-testi, Mann-Whitney U ve Pearson ki-kare testleri kullanıldı.

Bulgular: Karşılaştırmalı-tanımlayıcı araştırma, yaş ortalaması 12,45±2,71 olan 49 çocuk (14 kız, 35 erkek) ile yapılmıştır. Çalışma katılımcıları kanser tanılı (7 kız, 13 erkek) ve normal gelişim gösteren (7 kız, 22 erkek) çocuklar olmak üzere iki gruptan oluşmaktaydı. Kanser tanılı çocuklar grubu, tek görev koşulu altında daha düşük yürüme hızı (p<0,001) ve kadans (p<0,001) sergiledi. Bilişsel çift görev koşulu altında, kanser tanılı çocuklar grubunun daha düşük yürüme hızı (p<0,001) ve kadansı (p<0,001) vardı. Ayrıca yürüme hızı (p<0,001) ve kadans (p<0,001), motor çift görev koşulunda kanser tanılı çocuklar grubunda daha düşüktü. İki grubun çift adım uzunlukları ve çift görev maliyeti değerleri arasında fark yoktu (p>0,05).

Sonuç: Sonuç olarak, çalışma kanser tanılı çocukların tek ve çift görev yürüme parametrelerinde sapma olabileceğini göstermiştir. Kanser tanılı çocuklardaki tek ve çift görev yürüme parametrelerinin değerlendirilmesi, rehabilitasyon ihtiyaçlarının belirlenmesine katkıda bulunacaktır.

Anahtar kelimeler: Kanser; Çocuk; Yürüme analizi; Görev performansı; Rehabilitasyon.

Abstract

***Purpose**: This study aimed to compare single- and dual-task gait parameters between children with cancer (CC) and typically developing children (TDC).*

***Methods**: The gait parameters (gait speed, cadence, and stride length) assessed by the 10-meter walking test under single- and dual-task conditions and dual-task cost (DTC) was calculated. The t-test, Mann-Whitney U, and Pearson chi-square tests were used for comparisons.*

***Results**: The comparative-descriptive study was conducted with 49 children (14 females and 35 males) with a mean age of 12.45±2.71. The study participants consisted of two groups: CC (7 girls, 13 boys) and TDC (7 girls, 22 boys). The CC group exhibited lower gait speed (p<0.001) and cadence (p<0.001) under the single-task condition. Under the cognitive dual-task condition, the CC group had lower gait speed (p<0.001) and cadence (p<0.001). Also, gait speed (p<0.001) and cadence (p<0.001) were significantly lower under the motor dual-task condition in the CC group. There was no difference between the two groups ' stride lengths and dual-task cost values (p>0.05).*

***Conclusion**: Consequently, the study demonstrated that CC might have a deviation in single- and dual-task gait parameters. Assessments of single- and dual-task gait parameters in CC will contribute to the identification the rehabilitation needs.*

***Keywords**: Cancer; Child; Gait analysis; Task performance; Rehabilitation.*

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INTRODUCTION

Cancer, one of the chronic disorders, takes place among the most important health problems experienced during childhood in the world. Although the developments in the treatment methods such as chemotherapy and radiotherapy have recently increased the survival rate it is stated that these treatment methods can cause mental, cognitive and physical deficits in children with cancer.[1] Most studies on children with cancer (CC) reveal that the disease and its treatment cause long-term side effects on the musculoskeletal system, physical functions, gait, and cognitive skills.[1,2] The therapies used for CC can change the child's gait characteristics by adversely affecting the functioning and structure of the lower extremity or nervous system. Some studies assessing these changes have revealed that individuals with bone tumor lesions in lower extremities and nervous system tumors experience function loss and physical deficits.[3] In a study, it was determined that gait disorders were observed in children with bone and central nervous system tumors and all pediatric oncology individuals.[4] Active ankle dorsiflexion, gait parameters (stance, swing, and pre-swing phase), and walking efficiency were significantly impaired in a mixed childhood cancer survivor population compared with the control group in the study.[4] In addition, most studies have emphasized that children with chemotherapy-induced peripheral neuropathy exhibited electromyography, kinematic, kinetic, and spatiotemporal deviations throughout the gait cycle.[5,6]

The changes in cognitive functions occurring in CC are caused by the interference of complicated factors such as genetic predisposition, cancer type, age, and treatment method. The late effects on cognitive skills include attention and concentration deficits and dysfunction in working memory, processing speed, and executive functions.[3] Working memory generally refers to a system that storage a limited amount of information available for cognitive operations.[7] The developmental process of working memory in children is evaluated with a dual-task paradigm.[8] Dual-task is defined as performing two different tasks simultaneously.[9] Overlapping two tasks in working memory causes dual-task interference, leading to competition in cognitive resources with a reduction in working memory capacity, thus creating a less efficient performance when two tasks are concurrently performed.[8] Dual-task interference, known as dual-task cost (DTC), is the deficit occurring in the performance of one or both tasks as a result of performing two different tasks simultaneously and is calculated by the difference between dual-task performance and single-task performance.[10] For example, the gait speeds of individuals may decline while simultaneously performing a cognitive task.

Nowadays, dual-task exercises are included in rehabilitation programs for children with many motor and cognitive disorders.[11,12] Comparing the dual-task performance of CC with typically developing children (TDC) may be clinically helpful in guiding future treatments. Therefore, this study aimed to compare the gait parameters and DTCs under single-task and dual-task conditions between CC and TDC.

METHODS

Design

This study was a comparative-descriptive study performed by the principles published in the Helsinki Declaration of Human Rights. The Clinical Research Ethics Committee approved the study protocol of the Afyonkarahisar Health Science University (Number: 2021/144 Date: 05/02/2021). Before data collection, the children and guardians obtained written informed consent recommended by the World Health Organization Research Ethics Review Committee for clinical studies.

Participants

The sample of this study comprised CC receiving treatment in the pediatric hematology-oncology clinic of a university hospital or being followed up in the outpatient clinic in Afyonkarahisar. The TDC were healthy siblings of CC. The sample size was determined by G*Power V.3.1.7 (University of Kiel, Kiel, Germany) program. The inclusion criteria for the CC group were as follows: being between 9 and 18 aged of both genders,[13] with the ability to follow verbal instructions, having been diagnosed with an oncologic disease, receiving active treatment (chemotherapy, radiotherapy,

or combined therapy), and having no physical limitation or secondary disease. The exclusion criteria were as follows: staying in an isolated room or having an infection risk, having undergone lower extremity or spinal surgery, having a comorbid disease (physical, neurological, mental, cardiovascular, etc.), having cognitive impairment, or using any assistive device while walking. In addition, the study recruited age- and gender-matched healthy controls (TDC group) with the CC group. The inclusion criteria for the TDC group were as follows: being aged 9–18 years of both genders and with the ability to follow verbal instructions, and not having any diseases (physical, neurological, mental, or cardiovascular).

Measures

The study data were obtained from the pediatric hematology-oncology clinic and a local school between March-July 2021. The primary outcome measures included spatiotemporal gait parameters (gait speed, cadence, and stride length parameters) assessed by the 10-meter walking test under single- and dual-task conditions and calculation of DTC values.

Data were collected using a protocol approved by the researchers. The researchers were composed of a pediatric hematologist-oncologist, a pediatric oncology nurse, and two physiotherapists (one of the physiotherapists had 7-years of experience in pediatric rehabilitation and the other physiotherapist had gait assessment experience of over 10-years). A researcher (pediatric oncology nurse) who knew the CC in the clinic collected the demographic data according to family and child expressions. The other two independent researchers (two physiotherapists) performed the gait assessment together. The same researchers (all independent of the TDC group) assessed the TDC group similarly. All the assessments were conducted at an exercise and a playing room in the hematology-oncology clinic. During the assessments, none of the children had any problems with understanding the assessment instructions.

The effect size was accepted as d=0.875 which was obtained from gait speed results in the reference study; it was calculated that an 80% power could be obtained in a 95% confidence interval when at least 18 participants were included in each group in the study.[5]

Child information form

The child information form was used in the collection of demographic data. This form consisted of questions about sociodemographic and descriptive characteristics (age, gender, Body Mass Index [BMI], diagnoses, treatment received, etc.) of the children.[14]

Gait assessment

Gait parameters were assessed with the BTS G-Walk® (BTS, Italy) device using the 10-meter walking test under single- and dual-task conditions. G-Walk is an approved and reliable wearable wireless sensor device clinically used for gait measurements in children.[15,16] This device includes an accelerometer and gyroscope and can define spatiotemporal gait parameters while walking.

For the gait assessment, the participant's demographic data (age, height, and gender) was entered into the device software, and then the walking test was selected on the interface. Then, the BTS G-walk device was attached to the participant's L4-L5 intervertebral disc level with a belt during the test. Finally, the participant walked on a 10-meter flat surface at their usual pace with regular footwear. When the gait assessment was completed, the device automatically calculated the gait data, and the software automatically processed the information and presented it to the researchers in graphs and tables. An assessment required an average of 2 minutes. The children were allowed to rest for a sufficient time between the assessments.

Gait assessment under single-task conditions: The gait was assessed on a flat and firm surface without adding any cognitive or motor tasks (Figure 1, A).

Gait assessment under dual-task conditions was performed in two ways: Gait assessment in combination with a cognitive task (cognitive dual-task) and gait assessment in combination with a motor task (motor dual-task).

Cognitive dual-task (CDT): In this assessment, a 10-meter walking test and an auditory 1-back test were simultaneously performed. For the auditory 1-back test, the lists, including the stimuli numbers (0-9) to be remembered, were recorded with a female voice. The numbers were randomly put in an order so that no repeats (8-8; 2-2) and series (1-2-3; 7-8-

9) were included and presented as the participants could easily hear during the task. The participants had to remember the priory presented numbers and loudly tell a previous number (1-back) from the new number when the new number was presented. As soon as the participants said the first number, they started walking for the gait assessment. The participants continued to perform the 1-back test until the end of the walking.[17] (Figure 1, B)

Motor dual-task (MDT): The participant received the 10-meter walking test while carrying a glass of water (4 cm diameter, 90 g curb weight; 3/4 part of it was filled with water). The participant was asked not to pour the water during the assessment (Figure 1, C).[18]

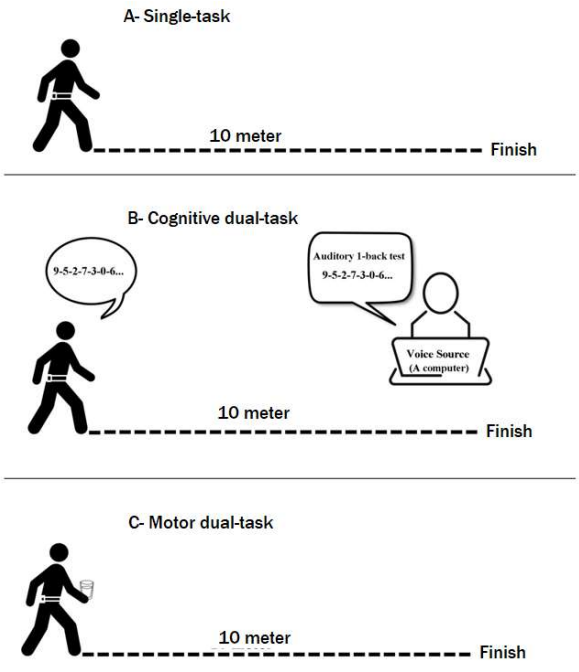

Figure 1. Gait assessments.

A trial test was performed before the walking tests, and rest was allowed after each. Finally, the DTC was calculated after the gait was assessed under single- and dual-task conditions (DTC= (single-task score – dual-task score)). A positive DTC value exhibits how much the performance of the individual gets worse during DT performance compared with the single-task conditions and how the performance cost increases.[8] Individuals generally use activities combining more than one task (multiple tasks) daily, but this combination increases the performance cost compared with single-tasks, which reveals the clinical importance of DT cost.[19]

Statistical analysis

IBM SPSS Statistics 21.0 (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0, Armonk, NY, USA: IBM Corp.) software program was used in data analysis. Any subjects with missing values related to gait parameters and descriptive characteristics were excluded from the analysis. The conformity of the data to normal distribution was assessed with the Shapiro-Wilk test. Normally distributed variables (single-task gait speed, single-task cadence, CDT gait speed, CDT cadence, CDT stride length, MDT cadence, MDT stride length, CDT DTC gait speed, CDT DTC cadence, MDT DTC gait speed) were revealed as mean ± SD, skewed distributions (age, BMI, single-task stride length, MDT gait speed, CDT DTC stride length, MDT DTC cadence, MDT DTC stride length) were indicated as median with interquartile range, and frequencies were used to present categorical variables (gender, diagnoses, type of treatment, treatment phases). For normally distributed data, the t-test was used, while the nonparametric Mann-Whitney U test was employed for skewed distributions. The chi-squared test was used for analyzing categorical variables.[20]

RESULTS

Fifty-seven individuals (24 in the CC group and 33 in the TDC group) were assessed for eligibility in the study. Seven participants who did not meet the inclusion criteria (3 children who were misdiagnosed or had comorbidities in the CC group, 4 who did not meet the age criteria in the TDC group) and had missing data (1 in the CC group) were excluded from the study. Eventually, the study was completed with a total of 49 individuals (14 female and 35 male participants) with a mean age of 12.45±2.71 and a mean BMI of 18.22±3.76 (Figure 2).

Descriptive data of the participants were presented in Table 1. Two groups were similar

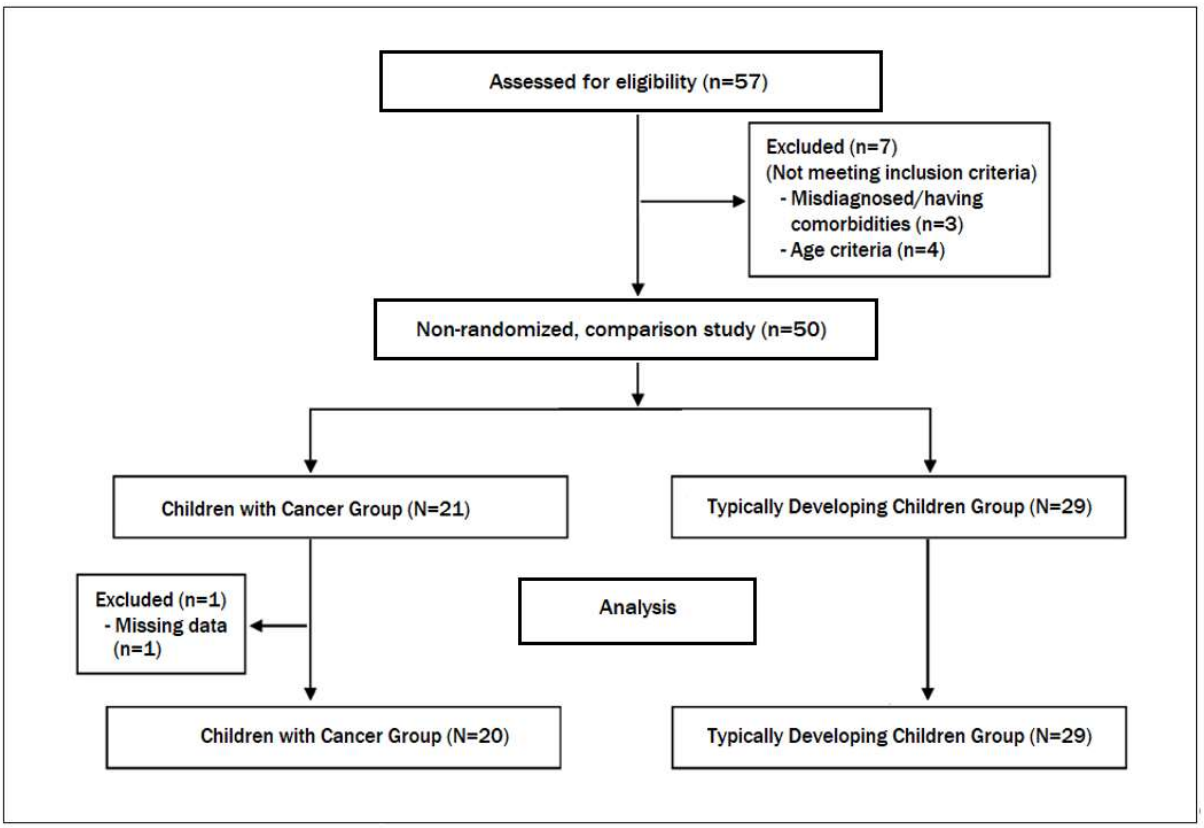

Figure 2. Flowchart of the study.

in terms of age (p=0.14), BMI (p=0.24), and gender (p=0.41).

Under single-task conditions, the CC group showed a significantly lower gait speed (t=-4.62; p<0.01) and cadence (t=-8.07; p<0.01) when compared to the TDC group. There were no differences between the two groups regarding stride length (U=239.50; p=0.30). The CC group exhibited a lower gait speed (t=-5.33; p<0.01) and cadence (t=-8.49; p<0.01) when compared to the TDC group under the CDT condition. Also, the two groups were similar in stride length (t=-1.25; p=0.27). The between-groups comparison indicated that the CC group had a significantly decreased gait speed (U=88.50; p<0.01) and cadence (t=-7.52; p<0.01) than the TDC group under MDT conditions. There were no differences between the two groups regarding stride length (t=-1.13; p=0.27) (Table 2).

There was no difference between CC group and TDC group in terms of DTC gait speed (t=0.19; p=0.85), cadence (t=1.21; p=0.23) and stride length (U=288.00; p=0.97) under CDT condition. Also, no significant differences between the two groups in terms of DTC gait speed (t=-0.32; p=0.75), cadence (U=236.00; p=0.27), and stride length (U=236.00; p=0.58) under MDT condition (Table 3).

Also, single- and dual-task gait parameters were compared between the CC who received chemotherapy and combined treatment in the study. However, no difference was found between the two groups regarding any single- and dual-task gait parameters (p>0.05).

DISCUSSION

Every year, about 400.000 children and adolescents are diagnosed with childhood cancer. The nature of childhood cancer and aggressive treatments considerably affect the motor and cognitive skills of the CC.[21,22] This study demonstrated that CC exhibited slower

Table 1. Characteristics of the participants.

	CC Group (N=20) Median (IQR)	TDC Group (N=29) Median (IQR)	p
Age (year)	12.00 (6.00)	11.00 (6.00)	0.14 (a)
Body Mass Index (kg/m²)	18.32 (7.29)	17.33 (3.21)	0.24 (a)
	n (%)	n (%)	
Gender (Female/Male)	7/13 (35/65)	7/22 (24/76)	0.41 (b)
Diagnosis			
Acute lymphoblastic leukemia (ALL)	12 (60)	-	-
Acute myeloid leukemia (AML)	2 (10)	-	-
Solid tumor (Ovarian, testicular, renal tumor)	6 (30)	-	-
Type of treatment			
Chemotherapy only	14 (70)	-	-
Radiotherapy only	-	-	-
Combined	6 (30)	-	-

CC: Children with Cancer. TDC: Typically Developing Children. (a): Mann-Whitney U Test. (b): Pearson's Chi Square Test.

Table 2. Intergroup comparisons of single- and dual-task gait parameters.

	CC Group (N=20)	TDC Group (N=29)	p
	X±SD	X±SD	
Single-task			
Gait speed (m/s)	0.97±0.18	1.24±0.22	<0.01 (c)
Cadence (steps/min)	104.72±10.67	128.56±9.82	<0.01 (c)
Stride length (m) (Median (IQR))	2.22 (0.43)	2.41 (0.69)	0.30 (a)
Cognitive Dual-task			
Gait speed (m/s)	0.74±0.18	1.02±0.18	<0.01 (c)
Cadence (steps/min)	91.56±12.53	118.60±8.14	<0.01 (c)
Stride length (m)	1.93±0.41	2.06±0.33	0.22 (c)
Motor Dual-task			
Gait speed (m/s) (Median (IQR))	0.82 (0.28)	1.17 (0.34)	<0.01 (a)
Cadence (steps/min)	100.91±11.78	122.55±8.40	<0.01 (c)
Stride length (m)	2.10±0.39	2.22±0.36	0.27 (c)

CC: Children with Cancer. TDC: Typically Developing Children. (a): Mann-Whitney U Test. (c): Independent t Test.

Table 3. Intergroup comparisons of dual-task costs.

	CC Group (N=20)	TDC Group (N=29)	p
	X±SD	X±SD	
Cognitive Dual-task			
Dual-task Cost-Gait speed	0.23±0.08	0.23±0.13	0.85 (c)
Dual-task Cost-Cadence	13.16±10.22	9.97±8.24	0.23 (c)
Dual-task Cost-Stride length (Median (IQR))	0.22 (0.34)	0.16 (0.31)	0.97 (a)
Motor Dual-task			
Dual-task Cost-Gait speed	0.10±0.06	0.11±0.11	0.75 (c)
Dual-task Cost-Cadence (Median (IQR))	3.25 (5.15)	3.97 (9.89)	0.27 (a)
Dual-task Cost-Stride length (Median (IQR))	0.15 (0.19)	0.34 (0.36)	0.58 (a)

CC: Children with Cancer. TDC: Typically Developing Children. a: Mann-Whitney U Test. c: Independent t Test.

gait speed and less cadence when walking than TDC single- and dual-task conditions (cognitive and motor). Interestingly, shifting from the single-task conditions to the dual-task conditions did not reveal more dual-task costs for CC compared with TDC. Nevertheless, this study indicated that CC had an inefficient gait pattern (in terms of gait parameters) under single- and dual-task conditions compared to TDC.

Gait analysis determines gait deviations and gait anomalies in clinics and research. There are many methods used in gait analysis.[23] One is the evaluation of gait kinematics by wearable sensors and comparison with normative values. In this study, when the gait parameters of the children receiving cancer treatment under single- and dual-task conditions were compared with the normative values and the control group, it was observed that the gait parameters deviated from the normal.[13] We think motor and cognitive impairments that develop in children with cancer may cause these gait deviations. Studies in literature have generally assessed the single-task gait parameters of CC developing peripheral neuropathy due to chemotherapy.

This study demonstrated that single- and dual-task gait speed decreased in CC. In one study comparing single-task gait parameters in children with cancer who had vincristine neuropathy with a healthy control group, it was found that CC who had vincristine neuropathy walked more slowly.[5] In a previous study, the single-task gait of children diagnosed with acute lymphoblastic leukemia (ALL) post-chemotherapy neuropathy and healthy controls was evaluated with 3D motion analysis systems and electromyography. As a result, it was found that the CC group with neuropathy exhibited a slower gait pattern.[6] In another study, single-task gait parameters in children receiving intensive cancer treatment and healthy controls were compared using the 10-meter walking test. The study data confirmed that children with cancer receiving intensive treatment were slower on the 10-meter walking test that was performed by fast walking speed (single-task) than healthy controls. However, there was no difference between the two groups in terms of the 10-meter walk test that was performed via preferred walking speed.[24] The results obtained in this study are similar to the results of other studies in the literature. However, to the authors' knowledge, there is no other study in the literature comparing dual-task gait speed in CC with TDC. Most studies in the literature have attributed slower walking in CC to neuropathy, decreased ankle joint motion, or motor impairments such as decreased ankle muscle strength following chemotherapy.[5,24] No studies have focused on the effect of cognition on gait speed.

Studies evaluating cadence in CC are limited in the literature. Only Gilchrist and Tanner[5] compared CC with neuropathy and healthy controls regarding cadence in single-task gait performance. They emphasized that there was no difference. In this study, cadence in single- and dual-task gait was reduced in CC. Alaniz et al.[25] compared the single-task gait of children with ALL suspected peripheral mononeuropathy with normative data and found parallel findings with our study and stated that cadence decreased in children with cancer. The differences between the results of the studies may be related to the different assessment methods used in the studies. More studies on cadence are needed.

In this study, the stride length of CC was similar to that of typically developing children in both single- and dual-task gait assessments. In Gilchrist and Tanner's study,[5] the step lengths of CC in single-task gait assessments were shorter than those of TDC. Wright et al.[6] also noted findings similar to Gilchrist and Tanner's study. Beulertz et al.[4] showed that in a mixed population of childhood cancer survivors, step lengths of cancer survivors were similar to those of TDC. No other study was found in the literature that evaluates stride length in single- and dual-task conditions in CC, as in our study. According to the authors, the similarity of the findings of this study with the study of Beulertz et al.[4] might be explained by the mixed populations of childhood cancer in both studies. Additionally, CC in the other two studies had a diagnosis of neuropathy, unlike our study.[5,6] Therefore, it is thought that a difference in step lengths may have been found in the other two studies.

The primary task evaluated in terms of dual-task in this study was walking. When a secondary task (motor or cognitive) was added to walking, a decrease in walking performance was observed in both CC and TDC. Gait performance

loss in both groups can be attributed to the interferences between primary and secondary tasks in the dual-task paradigm and is defined as dual-task cost.[26] According to the current findings, the increase in dual-task cost did not differ between CC and TDC, which is surprising because several studies on children with cancer have revealed that they are at a disadvantage compared to their healthy peers in cognitive and motor skills.[4,6] In the current study, single- and dual-task gait parameters were below the normative values compared to controls. Perhaps learning may have affected these results. In the study, dual-tasks were performed after the single-task. Learning the primary (walking) task and focusing the children's attention on the secondary task may have caused the value of the dual-task cost in both groups to be too low to distinguish between the two groups.

In this study, gait parameters were not affected by the type of treatment received by CC. To the knowledge of the authors, there is no study comparing gait parameters according to the type of treatment. However, regardless of the type of cancer, the risk of cognitive impairments due to cancer increases depending on age (starting treatment at a young age), cranial radiation therapy, parenteral or intrathecal methotrexate use, gender (female), and presence of comorbidities.[27] Researches indicate that therapeutic agents can affect gait and cause falls through neurotoxicity, with a combination of impairments in sensory, motor and cognitive domains.[28] Perhaps more disorders in gait parameters may be expected in the group receiving combined treatment. However, the treatment dose has a vital impact on the development of disorders caused by the type of treatment.[29] The similarity of gait parameters between the two groups may be explained by the effect of the different treatment doses applied.

Limitations

This study has some limitations. Firstly, the participants in this study were children with cancer from only a university hospital limiting the generalizability of the results. Secondly, performing single- or dual-task gait assessments in a nonrandomized order may have resulted in children learning the primary task, affecting study results. Finally, another limitation was that children's cognitive functions were not assessed in the study.

Conclusion

This is the first study assessing both single- and dual-task gait parameters in CC and reveals that the single- and dual-task gait parameters deviate in CC comparison with TDC. Therefore, single- and dual-task gait assessments in CC will contribute to the identification of children's rehabilitation needs and their inclusion in proper intervention programs (single- and dual-task training, etc.). Moreover, the risk of falling may decrease, and active participation in daily life may be encouraged for these children by single- and dual-task training. However, further studies evaluating single- and dual-task gait and calculating dual-task costs in children with CC are needed in the future.

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Authors' Contributions: **ETH:** study conception and design, data collection, analysis and interpretation of results, draft manuscript preparation; **HNÇÖ:** data collection, analysis and interpretation of results, draft manuscript preparation; **YEK:** data collection, draft manuscript preparation; **İE:** draft manuscript preparation

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ORIGINAL ARTICLE

Diyabetli bireylerde cinsiyetin ağrı, üst ekstremite fonksiyonları ve yaşam kalitesi üzerine etkisi

Influence of gender on pain, upper extremity functions, and quality of life in individuals with diabetes

Murat Ali ÇINAR[1], Zeynep İrem BULUT[1], Çiğdem Ayhan KURU[2], Yavuz YAKUT[1]

Öz

Amaç: Bu çalışma tip I ve tip II diyabetli hastalarda cinsiyetin ağrı, üst ekstremite fonksiyonları ve yaşam kalitesi üzerine etkisini araştırmak amacıyla planlandı.

Yöntemler: Web tabanlı kesitsel bir araştırma olan bu çalışmaya tip I ve tip II diyabeti olan toplam 130 hasta dahil edildi. Çalışmada, kol, omuz ve el sorunları anketi, Michigan el sonuç anketi, üst ekstremite ağrı şiddetine yönelik sayısal derecelendirme ölçeği, nöropatik ağrı anketi-Kısa Form, Dünya Sağlık Örgütü yaşam kalitesi anketleri kullanıldı.

Bulgular: Kadınların Michigan el sonuç anketine ait ağrı alt ölçeğindeki puanları erkelere göre daha yüksekken (p = 0,006), fonksiyon alt ölçeğine ait puanları ise erkeklere göre daha düşüktü (p=0,037). Kol, omuz ve el sorunları anketi içerisinde bulunan çalışma alt ölçeği puanlarına bakıldığında ise kadınların işlev düzeyinin daha düşük olduğu belirlendi (p=0,016).

Sonuç: Diyabetin ağrı, üst ekstremite fonksiyonu ve genel sağlık açısından kadın ve erkekler üzerinde farklı etkileri olabilir. Kadınların ağrı ve üst ekstremite fonksiyonu açısından erkeklerden daha fazla etkilendiği görüşündeyiz.

Anahtar Kelimeler: El, Diyabet, Üst ekstremite, Ağrı.

Abstract

***Purpose**: This study was planned to investigate the effect of gender on pain, upper extremity functions and quality of life in patients with type I and type II diabetes.*

***Methods:** A total of 130 patients with type I and type II diabetes were included in this study, which was a web-based cross-sectional study. In the study, arm, shoulder and hand problems questionnaire, Michigan hand outcome questionnaire, numerical rating scale for upper extremity pain severity, neuropathic pain questionnaire-Short Form, and World Health Organization quality of life questionnaires were used.*

***Results:** While women's scores on the pain subscale of the Michigan hand outcome questionnaire were higher than men (p=0.006), the scores on the function subscale were lower (p=0.037). When the working subscale scores of the disabilities of the arm, shoulder and hand questionnaire were examined, it was determined that the function level of women was lower (p=0.016).*

***Conclusion:** Diabetes has a different impact on men and women in terms of pain, upper extremity function, and overall health. Women appear to be more affected than men in terms of pain and upper extremity function.*

***Keywords:** Hand, Diabetes mellitus, Upper extremity, Pain.*

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INTRODUCTION

Diabetes mellitus (DM) is a multifactorial disease that is prevalent worldwide and results in musculoskeletal disorders in more than half of the patients.[1-4] It is estimated that between 2010 and 2030, diabetes will increase in adults by 69% in developing countries and 20% in developed countries.[5] Foot and ankle effects are present in 25% of patients with diabetes. Moreover, one-third of these patients have upper extremity problems.[3-5] Musculoskeletal disorders, such as carpal tunnel syndrome, Dupuytren's disease, tenosynovitis, and limited joint mobility are the most common upper extremity abnormalities. These complications mainly affect the patients' quality of life, functional status, and pain levels.[1-5]

Gender-specific differences impact the pathophysiology, incidence, prevalence, symptoms, course, and response to treatment of numerous diseases.[6] Understanding these differences is important in preventing disease complications and establishing treatment protocols. The physiological effects of sex-specific genes on certain organ systems result in sex differences.[6] In addition to affecting glucose homeostasis and insulin resistance, sex hormones may affect the prevalence, prognosis, and complications associated with the development of type I and type II diabetes.[1,2,6]

Several studies have examined gender differences in type I and type II diabetes.[6] In the literature, the importance of investigating gender-specific physiological differences in diseases with a complex pathophysiology such as diabetes has been emphasized.[6] Revealing these differences has an important place in minimizing the effects of diabetes.[6] In the understanding of evidence-based medicine, both types of diabetes and gender differences have an important place in the treatment of diabetes. [1-6] Investigating gender-specific differences such as glucose homeostasis and insulin may be important for the development of different and personalized treatment methods for diabetes.[1-6]

Although there are studies in the literature investigating the pathophysiological features specific to diabetes, no studies have been found examining how upper extremity functions, pain and quality of life differ according to gender in patients with diabetes.

This study examines the gender-specific differences in terms of upper extremity function, pain, and quality of life between patients with type I and type II diabetes. Another aim of the study is to investigate the effects of diabetes on women's health in terms of upper extremity functions and contribute to literature worldwide.

METHODS

Participants

This study was a web-based cross-sectional study. An online survey created using Google Forms was administered to individuals via a social application to their phone number directly between November 8, 2020 and January 29, 2021. Snowball sampling was used for reaching individuals, and researchers used their social network. Participants who fit the study criteria invited to fill the form. The volunteer participants were asked to suggest other contacts who met the research criteria, and the authors reminded their first circle of volunteers twice until reaching the target sample size. Inclusion criteria included individuals aged 18–65 years with type I or type II diabetes. Patients over the age of 65, those with various chronic disorders (cancer, rheumatic diseases, organ dysfunctions, neurological disease etc.), and those who had undergone surgery or were pregnant were all excluded from this study.

Overall, 130 individuals (72 women, 58 men) participated in the study. Researchers reached participants from five cities in different regions of Turkey (Istanbul, Ankara, Gaziantep, Hatay, and Trabzon). The fact that these selected cities were from different geographical locations and regions of Turkey was an important factor in making the choice. Participants were informed about the study, and informed consent was obtained prior to completing the online survey.

Measurements

The participants' sociodemographic and DM-specific information was obtained, and assessments were conducted to evaluate pain severity, neuropathic pain, functional level of the upper extremity, and quality of life.

Pain severity: The Numeric Rating Scale (NRS) was used to assess pain severity in the following upper extremity areas: shoulder,

upper arm, forearm, wrist, hand, and fingers. The NRS can be scored from 0 to 10 points, with 0 points indicating no pain and 10 points indicating the worst pain.[7]

Neuropathic pain: Neuropathic Pain Questionnaire-Short Form (NPQ-SF) was used to determine the presence of neuropathic pain, which has three subparameters: tingling pain, numbness, and increased pain due to constant touch. Pain severity is evaluated using a 0 (no pain) to 100 (the most severe pain) scale. Total scores below 0 indicated non-neuropathic pain, and scores above 0 indicated neuropathic pain.[8] The questionnaire was translated into Turkish, and its psychometric properties were conducted in the Turkish population.[9]

Upper extremity functional level: The Disabilities of the Arm, Shoulder, and Hand (DASH) was utilized to measure the functional status of the upper extremities.[10] The DASH consists of 30 items and special domains for musicians, sport, and work. The total score of the DASH ranges from 0 to 100, with high scores indicating a low level of function.[10] The DASH measures the three health outcomes identified by the ICF (International Classification of Functioning, Disability and Health), namely, impairments, activity limitations, and participation limitations.[11] The validity and reliability study of the DASH were conducted in the Turkish population.[12]

The Michigan Hand Outcomes Questionnaire (MHQ) was used to assess complaints on the hands and evaluate each hand separately. The questionnaire covers the following domains: function, daily activities, work performance, pain, aesthetics, and satisfaction. A high score in the pain domain indicates worsening, whereas a higher score in all other domains indicates improvement. The total score is calculated by adding the scores of the affected extremity and, if a bilateral extremity is affected, by calculating the average of the six domains.[13] This questionnaire is valid and reliable for the Turkish population.[14]

Quality of life: The World Health Organization Quality of Life Questionnaire-BREF (WHOQoL-BREF) assesses the quality of life, which consists of 26 items and four subparameters, including physical health, psychology, social relationships, and environment. This questionnaire is based on a Likert scale, with questions ranging from 1 to 5, with higher scores indicating a higher level of quality of life.[15] The Turkish version of the questionnaire has reasonable consistency, reliability, and construct validity.[16]

Statistical analysis

Statistical analysis was conducted using SPSS version 23 software (SPSS Inc., Armonk, New York, USA). The normal distribution of the data was tested using visual (histogram and probability graphs) and analytical methods (Kolmogorov–Smirnov/Shapiro–Wilk tests). Since all questionnaires used in the study did not show a normal distribution, the Mann–Whitney *U* test was used for comparing the differences between the results of the questionnaires. Descriptive analyses were presented using means and standard deviations and using medians and interquartile ranges for the non-normally distributed and ordinal variables (using frequency tables for the ordinal variables). The alpha level was set at 0.05 for all statistical significance tests. The paired *t* test was used for comparison of demographic variables between groups. According to G-power, it was decided to include a total of 128 (min.) individuals in the study (effect size=0.5).

Ethics

Ethical approval was obtained from the Hasan Kalyoncu University, Faculty of Health Sciences Ethics Committee. Patients were informed of the nature of this study, and a consent form was signed. Patients were informed of their right to withdraw from this study at any time. Approval was obtained with the decision number 2020/47 (date: 18.06.2020). This study has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans.

RESULTS

The study included 130 participants, 72 women (55.3%) and 58 (44.7%) men, aged 18 to 65 years. The dominant side was the right in 94% (n=68) of the women and 93% (n=54) of the men. The descriptive characteristics of the individuals are shown in Table 1.

Women had higher pain scores on the pain subscale of the MHQ (p=0.006). A significant difference was observed in the Increased Pain from the Constant Touch subscale of the NPQ-

SF (p=0.009), with women having higher scores (Table 2). Women had lower scores on the Function subscale of the MHQ (p=0.037). The score of the Work subscale of the DASH showed a lower level of function in women (p=0.016). Women had lower scores in the Physical Health subscale of the WHOQoL-BREF compared with men (p=0.006).

Scores of women and men were compared with respect to the type of DM. Women with type I DM (n=34) had better satisfaction scores (right: p=0.003; left: p=0.002) and better quality of life scores in relation to the Physical Health subscale (p=0.02) than type II DM (n=38) (Table 3). In men, there was no significant difference in relation to DM type (type1=20, type 2=38) (p > 0.05) (Table 4).

DISCUSSION

DM is a significant health policy issue. Upper extremity symptoms affect many aspects of health in patients with DM. The results of this study showed that the effects of DM were different between men and women. Women reported higher levels of pain intensity and lower functional levels and quality of life compared with men. We believe that our study can contribute to the literature in terms of gender-specific differences in diabetes and provide a different perspective in the development of new strategies to improve the health of individuals with diabetes.

It is stated in the literature that pain affects 25% of the world's population and that demographic characteristics, psychosocial characteristics and hormonal characteristics are important when differences between genders are examined. Since there was no difference between the groups in our study, we think that demographic characteristics are not effective among the factors affecting pain. [17-19] Women have been reported to complain of chronic pain and peripheral neuropathic pain more than men.[18, 19] In our study, although there was no statistical difference between male and female genders in neuropathic pain, it was found that women had more pain in the pain subheading of the MHQ questionnaire, which could be due to their lower pain threshold than men.[18] In a study by Abraham et al., a higher incidence of neuropathic pain was found in women with DM.[18] In our study, no difference was found in neuropathic pain between the male and female gender. We believe that patient-reported outcomes may be insufficient in the evaluation of neuropathic pain. In addition, it was observed that women had a higher score in the pain subparameter of the MHQ.

In our study, although there was a difference in pain in the MHQ subscale in men and women, the absence of pain in the visual analog scale may be because the way the MHQ asks about pain includes biopsychosocial characteristics, and participants were better able to perceive the questions in the MHQ and better describe the characteristics of pain.

In the MHQ, the right hand was more affected in the activities of daily living in women. In this study, the percentage of those whose dominant side was the right was the greatest in the male and female groups. However, we think that this difference may be due to the fact that women in the society in which the study was conducted have more domestic roles after work than men, although the majority of those with the right dominant side were present in both genders. Women had worse DASH-work scores than men. The fact that they have both work and personal activities may have caused more pain in women. Because DM increases pain more in women, pain-related programs should be implemented in the early stages of rehabilitation in women with DM and included in the treatment program of vocational rehabilitation practices.[19,20]

In a study published in 2022 by Pester et al., they emphasized that the acceptance of the presence of pain sensation varies between sexes.[21] In particular, they stated that men, due to their social beliefs, thought that accepting pain would make them weak, and they reported that they felt less pain in pain assessments than women.[22] Again, in the same study, it was reported that women had no difficulty in accepting the presence of pain compared with men.[21] In another study conducted in 2022, it was stated that gender roles may cause differences in the perception of pain in men and women.[19] Natalie et al. stated that different types of pain may cause different effects in men and women.[22] They emphasized that the incidence of chronic pain is higher in women and that the severity of acute pain is higher.[22] In this study, we are of the opinion that gender affects

Table 1. Demographics of participants.

	Women (N=72)	Men (N=58)	
	X±SD	X±SD	p
Age (years)	45.74±14.67	50.90±9.49	0.167
Body mass index (kg/m^2)	29.03±7.12	28.18±6.04	0.731
Duration of diabetes (years)	9.22±7.73	8.24±6.78	0.638
Duration of insulin use (years)	6.35±8.19	5.29±6.73	0.913

Table 2. General results regarding the genders.

	Women (N=72)	Men (N=58)	
	X±SD	X±SD	p
Michigan Hand Outcomes Questionnaire			
MHQ total	60.51±9.89	59.78±11.86	0.789
Function of right hand	73.75±21.91	74.40±19.91	0.812
Function of left hand	73.47±22.59	67.93±27.80	0.354
Function of total hand	73.61±20.44	71.16±22.53	0.711
Right hand: Daily living	85.14±18.93	90.09±18.39	0.037*
Left hand: Daily living	80.49±23.14	80.69±29.76	0.402
Both hands: Daily living	78.67±20.02	83.87±21.03	0.065
Work performance	47.64±21.40	47.93±22.15	0.895
Pain	21.60±17.81	13.31±15.48	0.006*
Aesthetics: right	70.31±26.49	74.46±29.53	0.228
Aesthetics: left	73.35±24.91	68.21±32.28	0.589
Satisfaction: right	67.42±23.75	72.41±19.38	0.163
Satisfaction: left	71.93±23.30	69.68±24.46	0.825
Disabilities of the Arm, Shoulder and Hand (DASH)			
Total	23.94±23.15	29.97±21.92	0.050*
Work (Women, n=43; Men, n=40)	30.81±28.20	15.73±20.75	0.016
Pain (Visual analog scale-VAS, cm)			
Shoulder	1.90±2.53	1.74±2.45	0.463
Upper arm	1.24±2.02	1.33±2.14	0.937
Elbow	0.85±1.55	1.21±2.43	0.534
Forearm	0.93±1.73	1.21±2.17	0.714
Wrist	1.36±2.12	1.43±2.46	0.604
Hand	1.06±1.91	1.60±2.55	0.502
Thumb	1.04±1.96	1.07±2.08	0.611
Second finger	0.78±1.57	1.12±2.09	0.513
Third finger	0.61±1.47	1.21±2.26	0.129
Forth finger	0.56±1.47	1.02±1.96	0.069
Fifth finger	0.65±1.55	0.91±1.79	0.256
Neuropathic Pain Questionnaire-Short Form (NPQ-SF)			
Tingling pain	−0.54±0.53	−0.68±0.44	0.164
Numbness	−0.63±0.57	−0.72±0.55	0.395
Increased pain due to touch constant	−0.91±0.40	−1.10±0.28	0.009*
Word Health Organization Quality of Life Questionnaire (WHOQoL)			
Physical health	12.36±3.43	13.67±2.70	0.006*
Psychologic	12.38±3.62	13.15±2.87	0.208
Social relationships	12.80±4.17	13.47±3.26	0.556
Environment	13.51±3.75	13.12±2.82	0.344

*p<0.05.

Table 3 General results regarding the type of diabetes in women (N=72).

	DM Type I (N=34)	DM Type II (N=38)	
	X±SD	X±SD	p
Michigan Hand Outcomes Questionnaire			
Total	62.69±10.18	58.55±9.32	0.112
Function of right hand	76.03±21.13	71.71±22.67	0.491
Function of left hand	77.94±19.58	69.47±24.54	0.193
Function of total hand	76.99±19.58	70.59±20.98	0.190
Right hand: Daily living	88.09±15.33	82.50±21.52	0.293
Left hand: Daily living	85.74±18.67	75.79±25.85	0.108
Both hands: Daily living	81.30±19.08	76.32±20.80	0.335
Work performance	46.62±23.18	48.55±19.93	0.688
Pain	20.15±18.11	22.91±17.67	0.600
Aesthetics: right	72.61±25.33	68.26±27.66	0.614
Aesthetics: left	73.53±24.62	73.19±25.50	0.995
Satisfaction: right	75.49±22.40	60.20±22.84	0.003*
Satisfaction: left	80.51±22.02	64.25±21.93	0.002*
Disabilities of the Arm, Shoulder and Hand (DASH)			
Total	17.99±20.44	29.25±24.37	0.052
Work (DM Type I, n=19; DM Type II, n=24)	30.92±32.17	30.73±25.33	0.812
Pain (Visual analog scale-VAS, cm)			
Shoulder	1.35±1.77	2.39±2.99	0.150
Upper arm	1.15±1.58	1.32±2.36	0.612
Elbow	0.59±1.13	1.08±1.84	0.297
Forearm	0.74±1.50	1.11±1.91	0.243
Wrist	0.88±1.30	1.79±2.59	0.152
Hand	0.85±1.33	1.24±2.31	0.649
Thumb	0.65±1.20	1.39±2.41	0.143
Second finger	0.50±1.19	1.03±1.82	0.061
Third finger	0.59±1.21	0.63±1.68	0.994
Forth finger	0.47±1.19	0.63±1.70	0.508
Fifth finger	0.74±1.42	0.58±1.67	0.555
Neuropathic Pain Questionnaire-Short Form (NPQ-SF)			
Tingling pain	−0.53±0.56	−0.55±0.50	0.959
Numbness	−0.62±0.68	−0.63±0.46	0.816
Increased pain due to touch constant	−0.93±0.41	−0.89±0.40	0.694
Word Health Organization Quality of Life Questionnaire (WHOQoL)			
Physical health	13.39±3.73	11.43±2.88	0.020*
Psychologic	12.73±3.69	12.07±3.59	0.360
Social relationships	13.06±4.37	12.56±4.03	0.517
Environment	13.19±3.71	13.80±3.82	0.312

*p<0.05.

Table 4 General results regarding the type of diabetes in men (N=58).

	DM Type I (N=20)	DM Type II (N=38)	
	X±SD	X±SD	p
Michigan Hand Outcomes Questionnaire			
Total	59.40±12.73	59.97±11.55	0.800
Function of right hand	77.50±20.81	72.76±19.51	0.414
Function of left hand	73.00±25.77	65.26±28.78	0.353
Function of total hand	75.25±21.90	69.01±22.85	0.303
Right hand: Daily living	89.00±14.38	90.66±20.34	0.068
Left hand: Daily living	81.25±23.89	80.39±32.72	0.273
Both hands: Daily living	82.86±19.31	84.40±22.12	0.552
Work performance	45.25±21.67	49.34±22.55	0.396
Pain	15.03±17.24	12.41±14.62	0.506
Aesthetics: right	65.94±29.97	78.95±28.68	0.103
Aesthetics: left	64.69±32.52	70.07±32.43	0.430
Satisfaction: right	71.25±19.02	73.03±19.80	0.570
Satisfaction: left	74.17±20.40	67.32±26.29	0.461
Disabilities of the Arm, Shoulder and Hand (DASH)			
Total	23.58±21.81	33.33±21.50	0.056
Work (DM Type I, n=14; DM Type II, n=26)	12.95±20.43	17.23±21.16	0.347
Pain (Visual analog scale-VAS, cm)			
Shoulder	1.40±2.23	1.92±2.57	0.777
Upper arm	1.20±1.96	1.39±2.25	0.923
Elbow	1.00±2.15	1.32±2.59	0.873
Forearm	1.00±1.72	1.32±2.39	0.706
Wrist	1.30±2.34	1.50±2.54	0.842
Hand	1.20±2.07	1.82±2.77	0.864
Thumb	1.00±1.56	1.11±2.32	0.347
Second finger	0.70±0.98	1.34±2.46	0.955
Third finger	0.75±0.97	1.45±2.69	0.804
Forth finger	0.75±1.02	1.16±2.31	0.766
Fifth finger	0.70±0.98	1.03±2.10	0.794
Neuropathic Pain Questionnaire-Short Form (NPQ-SF)			
Tingling pain	−0.53±0.46	−0.75±0.42	0.071
Numbness	−0.67±0.48	−0.75±0.58	0.275
Increased pain due to touch constant	−0.97±0.33	−1.17±0.23	0.031*
Word Health Organization Quality of Life Questionnaire (WHOQoL)			
Physical health	12.88±2.21	14.09±2.87	0.074
Psychologic	12.30±2.99	13.60±2.73	0.103
Social relationships	13.13±3.52	13.65±3.15	0.384
Environment	12.18±2.77	13.62±2.75	0.056

*p<0.05.

how pain is perceived clinically, as women experience more pain than men. In addition, rehabilitation processes for the treatment of pain may vary according to gender. Therefore, we believe that gender-specific research is important for clinical trials to understand the basic mechanisms of pain and to be able to develop personalized pain treatment. In 2022, Ercan et al. investigated the differences in pain in the musculoskeletal system according to gender in a certain occupational group.[23] Although women have more musculoskeletal problems than men, they have similar characteristics in terms of pain. However, in the same study, it was stated that as women's love for their profession increased, their perception of pain also decreased, but upper extremity problems were more common in men.[23] In this study, it was observed that women felt more pain according to the DASH-work score. However, most of the women participating in the study were housewives. Roles at home and satisfaction levels were not evaluated. We believe that there is a need for studies that also evaluate the satisfaction and happiness levels of women from their roles in home life.

Farina et al. evaluated the patients with DM with coronary artery diseases was in terms of gender and reported that women with DM and cardiovascular disease were worse than men.[24] In this study, women were found to be more affected in the physical health subheading of the WHOQoL-BREF, which includes questions, such as sleep quality, activity of daily living, and working capacity. Therefore, we think that the impact of diabetes on women may be worse in terms of physical health as well.

The effects of diabetes type may also differ in men and women. Although the effects of type I and type II diabetes on upper extremity function and pain were similar in men, the effects of type II diabetes were higher than type I diabetes on upper extremity functions and pain in women. Decreased quality of life in type II diabetes may be more affecting women of advancing age.[6] Additionally, studies that include only type I diabetes or only type II diabetes patients may contribute more to the literature.

Limitations

Due to the covid-19 pandemic at the time of the study, patients could not be evaluated face to face. Therefore, only patient reporting measurement methods were used as the measurement method (DASH, Michigan, etc.). Not being able to use more specific hand dexterity tests is also a limitation of the study.

Conclusion

Although the focus is mostly on the lower extremity functions and gait and quality of life in diabetes, the upper extremity, which affects the quality of life and functionality, may be affected at different levels by the type of diabetes and the gender of patients with diabetes. Although these patients did not have neuropathic pain, hand and upper extremity functions were affected.Due to the differences in the DASH and MHQ in patient reporting measurement methods, there is a need for studies in which specific manual dexterity tests are performed.There is a need for studies in which specific hand dexterity tests are performed because of the differences between DASH and Michigan measurement methods for patient reportin.

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ORIGINAL ARTICLE

Relation between balance, functional mobility, walking endurance and participation in ambulatory children with spastic bilateral cerebral palsy - Balance and participation in cerebral palsy

Yürüyebilen spastik bilateral serebral palsili çocuklarda denge, fonksiyonel mobilite, yürüme enduransı ve katılım arasındaki ilişki - Serebral palside denge ve katılım

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Abstract

Purpose: This study aimed to investigate the relationship between balance, functional mobility, walking performance and level of participation in ambulatory children with cerebral palsy.

Methods: the study included 43 children with spastic bilateral cerebral palsy and 26 children with typical development. Mobility of children with cerebral palsy was evaluated with Gross Motor Function Classification System, in which 18 of them were in level I and 25 children in level II. Balance skills and functional mobility were evaluated with Pediatric Balance Scale, Timed Up and Go Test, and 1 Minute Walk Test in children with cerebral palsy and typical development. Pediatric Outcome Data Collection Instrument was used to assess the participation level of children of two groups. The differences between groups were determined by Kruskall Wallis test and the Spearman Correlation test was used to analyze the relationship between functional balance, activity, and participation.

Results: Compared to children with typical development, balance skills were found to be lower in children with cerebral palsy (p:0.001). Balance status were correlated positively with walking performance (r:0.631) and activity of participation (r:0.796), but negatively (r:-0.774) with functional mobility in children with cerebral palsy.

Conclusion: The impairment of balance skills in children with CP reduces the levels of mobility, transfer, functionality and participation in daily life activities. As dynamic balance skills increase, functional balance, mobility level and social functions also improve.

Keywords: Cerebral palsy, Participation, Postural balance.

Öz

Amaç: *Bu çalışma yürüyebilen serebral palsili çocuklarda denge, fonksiyonel mobilite, yürüme performansı ve katılım düzeyi arasındaki ilişkisinin araştırılması amacıyla yapılmıştır.*

Yöntem: *Çalışmaya bilateral spastik serebral palsili 43 çocuk ve tipik gelişim gösteren 26 çocuk dahil edildi. Serebral palsili çocuklarda mobilite Kaba Motor Fonksiyon Sınıflandırma Sistemi ile değerlendirildi; bunların 18'i seviye I, 25'i ise seviye II idi. Serebral palsili ve tipik gelişim gösteren çocuklarda, denge becerileri ve fonksiyonel hareketlilik, Pediatrik Denge Skalası, Süreli Kalk ve Yürü Testi ve 1 Dakika Yürüme Testi ile değerlendirildi. İki gruptaki çocukların katılım düzeyini değerlendirmek için Pediatrik Sonuç Veri Toplama Aracı kullanıldı. Gruplar arasındaki farklar Kruskall Wallis testi ile belirlendi ve fonksiyonel denge, aktivite ve katılım arasındaki ilişkinin analizinde Spearman Korelasyon testi kullanıldı.*

Bulgular: *Serebral palsili çocuklarda denge becerileri normal gelişim gösteren çocuklara göre daha düşük olduğu belirlendi (p:0,001). Serebral palsili çocuklarda denge durumu, yürüme performansı (r:0,631) ve katılım aktivitesi (r:0,796) ile pozitif, fonksiyonel hareketlilik ile ise negatif (r:-0,774) ilişkili olarak bulundu.*

Sonuç: *SP'li çocuklarda denge becerilerinin etkilenimi, hareketlilik, transfer, işlevsellik ve günlük yaşam aktivitelerine katılım düzeylerini azaltmaktadır. Dinamik denge becerileri arttıkça fonksiyonel denge, mobilite düzeyi ve sosyal işlevler de gelişmektedir.*

Anahtar kelimeler: *Serebral palsi, Katılım, Postural denge.*

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INTRODUCTION

Cerebral Palsy (CP) is a clinical picture seen in early childhood characterized by functional impairment that affects the development of movement and postural control.[1] Brain damage and neurological impairments like spasticity, muscle weakness, co-contractions and visual impairments can affect the development of movement and posture in children with CP. According to studies, children and adults with CP are have postural impairments that may affect on daily life activities. Balance is defined as the ability to maintain the body center of mass within the support surface and consists of vestibular, visual, auditory, proprioceptive and upper level premotor systems. Problems such as abnormal motor control, persistence of primitive reflexes, formation of contractures or abnormal posture seen in children with CP may negatively affect balance.[2] Children with spastic CP are divided into unilateral (hemiplegic) and bilateral (diplegic and quadriplegic) according to the body involvement.[2]

"Walking by falling" due to insufficient postural control is one of the conditions encountered in children with spastic diplegic or bilateral CP. Fear of falling can lead to restriction of activities, they may result in pain, injury and disability.[1,2]

Approximately 60-70% of children with bilateral CP walk independently with or without restrictions outside the house and at a greater distance[3]. They face challenges like physical limitations, poor socialization, limited recreational activities, and stigmatization. Children with bilateral CP have a reduced ability to adapt sensory and motor components of postural control that come up from environmental factors affecting their response to react to different threats or to recover from unexpected situations. Also, functional balance problems affect their walking activity, which is characterized by falls, reducing their confidence to perform daily life activities.[4] Ambulatory children with CP may participate in physical activities and sports depending on their physical preferences and environmental conditions. They can walk in most environments but may have difficulty balancing on long-distance walks, uneven surfaces, or crowded areas. Also, in the community, they can walk with physical assistance. They may need some modifications to take part in physical activities.[5]

Sahoo, Rege, Rao et al.[6] stated that children with CP had limited social participation in different contexts and activities by their level of severity of motor impairment. Since 2007, assessment of body structure and function, as well as activity and participation dimension in children with CP within the scope of International Classification of Functioning, Disability and Health: Children and Youth Version (ICF-CY) provided a holistic perspective according to World Health Organization. Supporting the social life roles of children with CP has been an important goal of rehabilitation approaches.[7]

In this study, it was hypothesized that in ambulatory children with spastic bilateral CP, functional balance performance was lower than those with TD and the level of participation would change as the balance performance of children changed. Therefore, this study aimed to show the differences in functional balance performance between children with bilateral CP and TD children by assessing practical and precise balance measurements in order to investigate the relationship among the functional balance performance, daily life activities, and participation status of children with spastic bilateral CP.

METHODS

Participants

This study was carried out in Hacettepe University, Faculty of Health Sciences, Department of Physiotherapy and Rehabilitation, Cerebral palsy and pediatric rehabilitation unit in order to evaluate the effect of balance disorders on activity and participation in ambulatory children with CP. The sample of the study was selected from the children with CP and their parents who came for home program education. Children included in this study were followed by a home tracking program like 2-3 days a week, by the same physiotherapist, regularly. Also, they were applying the home program given by the physiotherapist. The parents were informed about the study and written consent was obtained from those that received to take part in

the study. This study included ambulatory children who were diagnosed with spastic bilateral CP at GMFCS level I and II and their parents those who can read and write in Turkish, in the range of age from 6-12 years. Included children had no joint limitation or any presence of contractures. The most common walking patterns observed in the children included in the study were crouch gait and toe walking.

All included children with CP were using AFO for 4-6 hours per day. Exclusion criteria were: non-ambulatory children with CP, different clinical type (dyskinetic, ataxia, etc.), having a severe type of GMFCS level, having a chronic disease like asthma or respiratory problems, severe visual, cooperation or cognitive problem, botulinum toxin injection, or orthopedic surgery at last six months.

Since these assessment tests did not have cut-off values to show balance disorder in the Turkish population, these assessment methods were applied to 26 children with TD to differentiate them from children with CP and functional balance performances were compared. Inclusion criteria for children with TD were: being in the same age (6-12 years) with the other group of children, having no chronic disease and having no any fracture or orthopedic surgery for any reason in the last 6 months.

Sample size was calculated by the G*Power Version 3.1.9.6 analyses program. The sample size estimations were done according to an observed effect size of d=1.43 and reported for PBS total score between children with CP at GMFCS level I and II[8]. To obtain 95% power to detect a difference with a 95% confidence interval using a two tailed test, as a minimum 15 children with CP were required for each group.

Demographic data were taken from their parents: gender, age, diagnosis, use of the assistive device, and the existence of secondary problems. Gross motor function and functional balance performance measurements were applied in the clinical setting.

Measurements

Gross Motor Function Classification System (GMFCS): GMFCS was used to classify the gross motor functions of children with CP in five levels between level I and V and was created by Palisano, Rosenbaum, Walter et al.[9]. While children with CP of level I can walk and run at home, school or outside, but may need speed and coordination for some activities, children with CP of level V are those who need transport and assistance and have difficulties on maintaining movements of the upper and lower extremity.

In this study, ambulatory children were classified by a physiotherapist according to the Turkish version of GMFCS, which was prepared by Günel et al.[10] Children of level I can walk and climb and show motor skills like running and jumping but their speed is limited in balance and coordination. Children of level II can walk short distances indoors on smooth surfaces outside the home without the need for a hand-held mobility device, but they cannot run or jump. They may have difficulty walking long distances, uneven surfaces, or restricted areas. In the community, children can walk with physical assistance or hand-held mobility devices.[9]

Pediatric Berg Balance Scale (PBS): PBS was used to evaluate the balance control in children with CP and is composed of 14 items like sitting balance, standing balance, transfers, stepping, etc. Each item is scored 0-4 points and all of them are assessed as static balance, dynamic balance, and a total one[11]. Turkish version of the PBS has high interrater (ICC=0.915), and intra-rater (ICC=0.927) reliabilities in children with CP are as shown. Permission to use the Turkish version of the PBS obtained from the author and the Turkish version was used in this study.[12]

Timed Up and Go Test (TUG): TUG measures functional mobility, balance, and anticipatory postural control in children with CP. The test is applied three times and the mean score is used to name a result. If needed, assistive devices can be used for the lower extremity. The time of the test is calculated from the start position to the end one. The TUG test had high test-retest reliability (ICC=0.98–1.00) in children with CP.[13]

One Minute Walking Test (1MWT): 1MWT assesses the walking endurance and functional ability in ambulatory children with CP. Throughout the test, maximum walking speed is assessed during 1 minute in 20 meters distance. Then, dynamic balance and muscle performance are determined by test. The test-retest reliability of the 1MWT to assess walking speed is regarded as high (ICC=0.94).[14,15]

Pediatric Outcome Data Collection Instrument (PODCI): Turkish version of the PODCI, translated by one of the co-authors, was used in this study. The valid and reliable Turkish version of PODCI was used to assess the level of activity, participation, physical function, and functional health status in children with CP. The PODCI can be used in children with a range of ages from 2-18 years and contains the assessment of upper extremity functions (PODCI-UE) physical function, and sport (PODCI-S), transfers and mobility (PODCI-TM), pain (PODCI-P), happiness (PODCI-H) and expectations from therapy (PODCI-G). Test-retest reliability is shown to be high (Alpha=0.93, ICC=0.99).[16] The PODCI-parent questionnaire was applied one by one to mothers who were Turkish and high school graduates.

All the functional balance tests were applied on the same day by giving a rest time of 5-10 minutes between the tests.

Statistical analysis

Statistical analysis was done by IBM SPSS Statistics for Windows (Version 21.0. Armonk, NY: IBM Corp). Children were classified due to group of level I and level II according to GMFCS and TD ones. The compatibility of the data with normal distribution was reviewed visually (probability plots and histograms) and through analytical methods (Kolmogorov-Smirnov/Shapiro-Wilk's test). The measurement data were indicated as the mean and standard deviation (SD). The data indicated by numbers were evaluated as number (n) and percentage (%). The age, height, weight, body mass index, PBS, TUG, 1 MWT, PODCI sub-scales, and PODCI global scores were compared by Kruskal-Wallis Test. The relationship between balance status, walking performance, and participation levels were analyzed by Spearman Correlation Test. The value of statistical significance was set at $p<0.05$. Cohen's recommendations for characterizing the strength of a correlation coefficient were applied: 0.15-0.29, weak; 0.30-0.49, moderate; 0.50-0.99, strong.[17]

RESULTS

Demographic characteristics of children: due to age, height, and weight there were no differences between children of both groups. Forty-three children with spastic bilateral CP and twenty-six TD children were

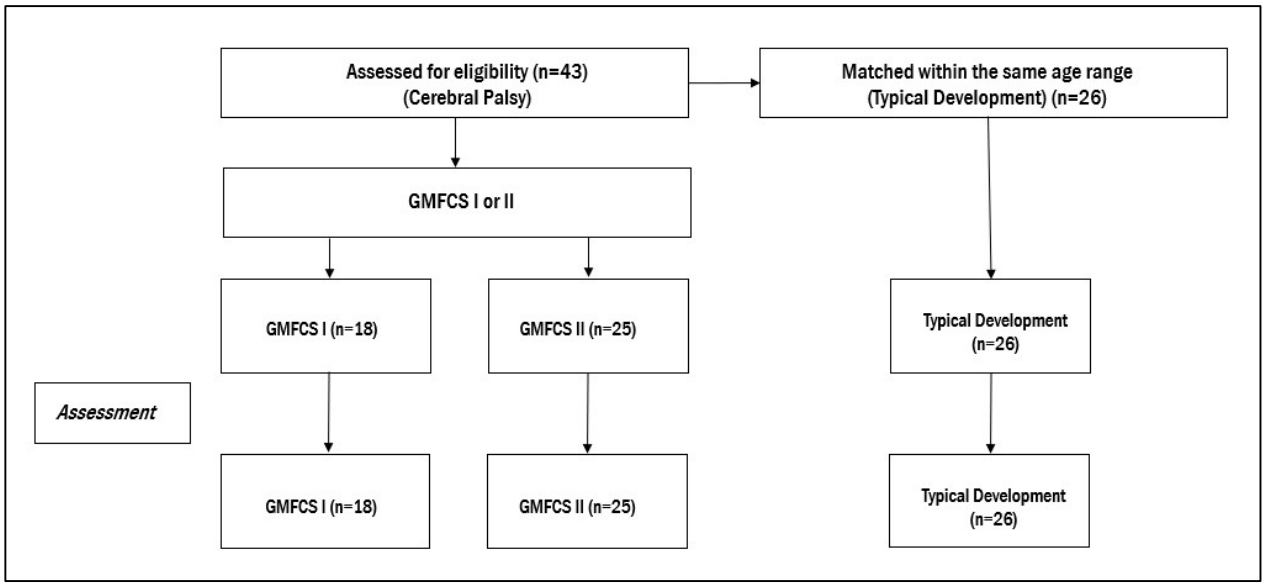

Figure 1. Flowchart of the study.

included in the study. Eighteen children with CP were in level I, twenty-five in level II of GMFCS. The mean age of children with GMFCS level I was 8.90±0.73 (8-10) years, the other group of GMFCS level II had a mean age of 9.20±1.58 (6-12) years, and TD children had 9.20±1.57 years (Table 1). Due to the functional balance skills of children, there were statistical differences between children with CP at GMFCS level I and II, and TD children (p:0.001) (Table 2). Children with CP had lower scores than children with TD.

It was found that there was a statistically significant difference in the scores obtained by the children in terms of the time they covered during walking ($p<0.05$, Table 2). According to the test results, the TUG mean score of children with CP was higher than the average score of TD children. Additionally, children of level I had a lower score of the TUG compared to those of level II (p:0.001). There were found differences between 1MWT scores between children with CP and TD ones (p:0.001) and there was a difference in the CP group where children of level I had better performance than children of level II under the 1MWT test (p:0.001) (Table 2).

Balance skills, walking performance and the levels of social participation of children with spastic bilateral CP included in this study were given in Table 3.

There were found a strong relationship between balance skills and participation level in daily life activities (r=0.796). Especially, a correlation between balance skills and the range of pain in children with CP (r:0.736) and also one with upper extremity skills (r:0.744) was found to be significant.

Participation scores of ambulatory children with spastic bilateral CP were negatively correlated with walking performance (r=-0.678) and moderately with one-minute walk test (r=0.513). Due to results, there were significant negative correlations between walking time and the level of pain in children with CP (r:-.610), also found moderate correlations between sport activities and distance of time recorded during one minute (r:0.512*) (Table 3).

While there was a strong negative correlation between functional balance and time taken during the test (r=- 0.774), there was a positive one with distance recorded in one minute (r =0.631) (Table 3).

DISCUSSION

This study examined functional balance performance, the relationship between balance status and activity-participation level of spastic bilateral children with CP in daily life and social life, and compared them with TD children. This study did found that balance problems besides motor functions were related to participation level in daily living activities where children with CP got lower points than their TD peers. Additionally, impairment of balance skills in children with CP can affect functionality, mobility, and transfer in daily life activities.

Due to the literature, there are limited tools to assess balance skills in children with CP. The PBS and TUG are two important tests used to define the quantitative values of the balance in children with CP.[15,16] Kembhavi, Darrah, Magill-Evans et al.[18] stated that the PBS was useful, functional, and easy to evaluate balance function. In this study in order to see the difference between children with CP and TD children, the PBS was used beside TUG and 1MWT. As expected, significant differences were found between groups where children with CP had lower scores than their TD peers. This study also investigated the difference between GMFCS level I and II due to balance skills where it was found a significant difference between the two groups. Balance scores of children of level I were higher than children of level II which showed us that despite improved mobility, children of level I had more coordination and balance problems especially on activities that require a speed or move over uneven places. Hassani, Krzak, Johnson et al.[15] compared TUG and 1MWT values between ambulatory children with CP and stated that those scores differ throughout GMFCS level, where the impairment level increases, time in TUG increases but the distance in 1MWT decreases. In this study, TUG and 1MWT were used to evaluate the differences between children with CP and children with TD and both groups differed from each other due to their scores and children with CP were affected despite their high level of mobility, dynamic balance skills and postural control. Under the GMFCS level, due to TUG, there was no big difference between children of level I and level II. It can be said that if impairment increases,

Table 1. Demographic characteristics of the children.

	Cerebral Palsied			
	GMFCS I (N=18)	GMFCS II (N=25)	Typical Development (N=26)	
	X±SD	X±SD	X±SD	p (a)
Age (years)	8.90±0.73	9.20±1.58	9.20±1.57	0.760
Height (cm)	131.90±9.01	126.40±7.02	137.35±13.56	0.170
Body weight (kg)	28.70±5.60	33.20±4.73	30.85±7.40	0.605

(a): Kruskal-Wallis Test. GMFCS: Gross Motor Function Classification System.

Table 2. Data obtained in groups and comparison between groups.

	Cerebral Palsied				
	GMFCS I	GMFCS II	Typical Development		
	X±SD	X±SD	X±SD	p (a)	(b)
One Minute Walk Test (1MWT) (m)	60.30±6.70	53.70±13.34	71.50±11.12	<0.001	I-TD, I-II, II, TD
Timed Up and Go Test (TUG) (sec)	8.46±1.00	9.10±1.19	6.40±0.94	<0.001	I-TD, I-II, II, TD
Pediatric Balance Scale (PBS)	50.60±2.95	46.60±6.02	55.85±0.56	<0.001	I-TD, I-II, II, TD
PODCI					
Upper Extremity	78.30±4.44	68.08±4.69	95.50±11.86	<0.001	TD-II, TD-I
Transfer	84.60±4.47	78.67±4.53	97.73±5.86	<0.001	TD-II
Sport	67.20±5.18	48.42±4.44	90.18±16.09	0.007*	TD-II
Pain	86.10±6.48	76.67±4.77	97.32±6.91	<0.001	TD-II, TD-I
Happiness	75.20±4.78	71.08±2.93	95.41±11.89	0.013*	TD-II
Global	81.90±4.99	64.92±5.05	94.92±8.36	<0.001	TD-I, TD-II, I-II

* p<0.05. (a): Kruskal-Wallis Test. (b): Differences between two paired comparisons. PODCI: Pediatric Outcome Data Collection Instrument. GMFCS: Gross Motor Function Classification System.

Table 3. The relationship among the functional balance tests and participation level of ambulatory children with spastic bilateral cerebral palsy (N=43).

	Pediatric Balance Scale (PBS)	Timed Up and Go Test (TUG)	One Minute Walk Test (1MWT)
	rho	rho	rho
Pediatric Outcome Data Collection Instrument			
Upper Extremity	0.744**	-0.566**	0.473**
Transfer	0.595**	-0.457**	0.371**
Sport	0.460**	-0.547**	0.512**
Pain	0.736**	-0.610*	0.535*
Happiness	0.503**	-0.369*	0.300*
Global	0.796*	-0.678*	0.513**
Timed Up and Go Test (TUG)	-0.774**		
One Minute Walk Test (1MWT)	0.631**		

* p< 0.05. ** p<0.01. rho: Spearman Correlation coefficient.

the time required to complete TUG will increase too. Otherwise, 1MWT differed between two groups where emphasized that by the increasing of GMFCS level, walking distance will decrease.

Gan, Tung, Tang et al.[19] stated a negative relationship between the PBS and TUG scale, high PBS scores were associated with decreased walking speed and increased walking time. They found a strong correlation between motor function and balance skills, where the PBS was found to be an evaluation of standing and walking abilities under the balance functions. In the current study, there was a positive strong correlation between balance activity and functional mobility, and a negative strong one with walking performance. Development of dynamic balance and static balance skills in children with CP would lead to better motor performance, faster-walking speed of the walk, and longer walking distance. The results were in the same line as those of Gan, Tung, Tang et al.[19]

Barnes, Linton, Sullivan et al.[20] investigated a study that established the values of Parent PODCI by age and GMFCS in ambulatory children with CP. Children with CP scored between 72.9-81.3 for children of GMFCS-I and 66.6-73.3 for those with GMFCS-II. In this study, ambulatory children with spastic bilateral CP had lower points than children with TD. The results were divided into two groups, under the GMFCS level and due to PODCI-Global, children of GMFCS Level I (81.90) had higher results than those of level II (64.92). Although being a functional children, group of GMFCS-II level are those who need physical support to carry out their transfers in the community, which demonstrates their difference from group of GMFCS-I level.

Despite PODCI global results, there were found differences between PODCI-UE, Transfer, Sport, and Pain. According to the PODCI-UE results, compared to children of level I, which has no restrictions in performing daily activities, it can be deducted that being a GMFCS-II child, alternative ways may be needed to perform some hand activities.

Due to the results of this study, it can be stated that the increase in the level of GMFCS affects functions such as transfer and mobility. As the capacity of children with CP to perform functional skills increases, their transfer and mobility levels will be positively affected, and that these can have an effect on the levels of participation in areas such as social function and self-care under daily life activities and that their level of independence will increase. The type of CP, muscle strength, body composition, and gait disturbance are the components that determine the GMFCS level. The development of gross motor functions in children with CP is important in terms of participating in daily life activities and increasing the quality of life. The decrease in the severity of the exposure may cause an increase in walking activity in children with CP and reduce the time during walking. As the walking performance increases, the individual can also improve the parameters under walking and participate in daily life activities.

An increase of physical state for children with CP means having more endurance and muscle force for the sports skills and this leads them to reverse to their TD peers. Being pre-adolescents, in adolescence, aware of their physical performance, and increasing their body awareness may affect their average scores. This will impact social activities especially. Under the PODCI-Pain, the presence of spasticity may bring pain together with the increase in the intensity of the exposure and the pain can increase especially towards adolescence.

Mehraban, Hasani and Amini[21] investigated on participation activities of school-aged children with CP and emphasized that participation played an important role in the health and development of children was an influential factor in gaining independence in adulthood. The main goal of rehabilitation for school-age children with CP was to develop independence in self-care and mobility. Oeffinger, Gorton, Bagley et al.[22] stated that in addition to insufficient physical activity, decreased muscle strength, spasticity, balance-coordination disorders, and gait disorders, environmental and personal factors were also that limit the daily life activities of children with spastic bilateral CP. PODCI-Global results differed between two groups based on the purpose that mild impairment harmed their daily life activities and participation state that children with spastic bilateral CP may need some modifications to take part in physical activities and social participation. By being a child with an ability to walk, run and jump without assistance they may participate in sports activities depending on their physical

preferences and environmental conditions. In the current study, strong results were found between balance status and daily life activities, and participation level.

Children with CP, as one of the most impaired group under the children with disabilities, are face to face with limitations in activities, lower involvement in the community, sport, and recreational activity which can affect their mood, cognitive and anxiety state.[23,24] Moraes, Copetti, Angelo et al.[25] also found a strong correlation between balance skills and mobility, social functions, and self-care activities in a study composed of 15 children with CP aged 5-15 years old and stated that balance development would be reflected on functional balance too. PODCI was used to evaluate the performance in daily life activities of children with CP and found a moderate result between PBS and the items of PODCI, especially in physical, sport, and global functions. In children with CP, the development of balance skills and motor performance affect their daily activity. Children of level I-II of GMFCS were included and so the increase of impairment level can impact transfer and mobility functions. By the improvement of functional and balance skills of children with CP, an increase of transfer and mobility state will lead to enhancement of self-care, social function, and also sport and physical performance.[26-28] In this study, a strong relation were found between balance skills and participation activities so the increase in balance skills, motor performance, and capacity in children with CP affects the level of activity and participation in daily life. Considering that included children have levels of GMFCS-I and II , it can be stated that the increase in the level of influence affects functions such as transfer and mobility. Increasing social participation and daily life activities in children with CP will make them more functional and will increase their mobility level and speed by decreasing the time required to complete the activity and decrease the gait distance.

As the capacity of children with CP to perform functional skills increases, their transfer and mobility levels will be positively affected and these will have an effect on the levels of participation in areas such as social function and self-care under daily life activities, so their independence level will be increased.

Limitations

The study included only children with spastic bilateral CP. Children with spastic unilateral CP weren't included in order of having one half of the body unimpaired and this could affect the balance results. One of our limitations was lack of technological-based balance assessments was one of our limitations. Also, the absence of spasticity and range of motion evaluation were the other limitations in order to have a more detailed results.

Conclusion

Loss of balance in children with spastic bilateral CP related to low functionality and limited participation levels. Balance impairment is associated with walking performance, children with CP included in this study were characterized by crouch gait and toe walking. The development of dynamic balance may increase functional balance, mobility level, and social functions of children with spastic bilateral CP. Especially, low functional balance performance may be one of the key barriers for limited social participation of ambulatory children with spastic bilateral CP. Looking forward, it is thought to be important to evaluate functional balance and coordination problems with a more detailed and practical in clinical settings and also in different environments (home, school, or community) in a more involved population with different clinical types of CP. In the literature, it is noteworthy that there are fewer evaluations of balance and coordination disorders in children with CP compared to children with typical development. We believe that our study will contribute to the evaluation of the effects of balance and coordination problems of children with CP on their activity and participation levels compared to typically developing children.

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