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Prof. Dr. Muhammed KILINÇ, Hacettepe University, Faculty of Physical Therapy and Rehabilitation, Department of Physiotherapy and Rehabilitation, Ankara, Türkiye. muhammed.kilinc@hacettepe.edu.tr

Prof. Dr. Şenay ÜNSAL ATAN, Ege University, Faculty of Nursing, Department of Nursing, İzmir, Türkiye. senay.unsal.atan@ege.edu.tr

Prof. Dr. Dilek AVCI, Bandırma Onyedi Eylül University, Faculty of Health Sciences, Department of Nursing, Balıkesir, Türkiye. davci@bandirma.edu.tr

Assoc. Prof. Ayşe TAŞTEKİN OUYABA, Afyonkarahisar Health Sciences University, Faculty of Health Sciences, Department of Nursing, Afyonkarahisar, Türkiye. ayse.tastekin@hotmail.com

Assoc. Prof. Biriz ÇAKIR, Kırıkkale University Faculty of Health Sciences Department of Nutrition and Dietetics, Kırıkkale, Türkiye. birizcakir1@gmail.com

Assoc. Prof. Tuba ÖZAYDIN, Selçuk University, Faculty of Nursing, Department of Nursing, Konya, Türkiye. tuba_demirel_70@hotmail.com

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COMPARISON OF INDIVIDUALS WITH MIGRAINE AND TENSION-TYPE HEADACHE IN TERMS OF PAIN, PHYSICAL ACTIVITY LEVEL AND TEMPOROMANDIBULAR DISORDER SEVERITY

MİGREN VE GERİLİM TİPİ BAŞ AĞRISINA SAHİP BİREYLERİN AĞRI, FİZİKSEL AKTİVİTE DÜZEYİ VE TEMPOROMANDİBULAR BOZUKLUK ŞİDDETİ AÇISINDAN KARŞILAŞTIRILMASI

Özlem Akkoyun Sert[1], Kamil Yılmaz[2], Ümit Yüzbaşıoğlu[3], Buse Kılınç Özay[4], Melike Müsevitoğlu[5*], Bahriye Horasanlı[6]

[1]Department of Physiotherapy and Rehabilitation, Faculty of Health Sciences, KTO Karatay University, Konya, Türkiye

[2]Department of Orthosis Prosthesis, Faculty of Health Sciences, On Dokuz Mayıs University, Samsun, Türkiye

[3]Department of Therapy and Rehabilitation, Vocational School of Health Services, Toros University, Mersin, Türkiye

[4]Gülhane Institute of Health Science, University of Health Sciences, Ankara, Türkiye

[5]Department of Therapy and Rehabilitation, Vocational School of Health Services, Karamanoglu Mehmetbey University, Karaman, Türkiye

[6]Department of Internal Medical Sciences, Faculty of Medicine, KTO Karatay University, Konya, Türkiye

ABSTRACT

Objective: The aim of this study was to compare individuals with migraine and tension-type headache (TTH) in terms of pain, physical activity level and severity of temporomandibular disorder.

Method: Individuals (n=48) between the ages of 18 and 45 who participated in the study were divided into two groups by being diagnosed with migraine or TTH by a neurologist. Pain severity was evaluated with the Visual Analogue Scale (VAS), headache impact level with the Headache Impact Test (HIT-6), Pressure-Pain Threshold (PPT) with the J-Tech Digital Algometer device, physical activity level with the International Physical Activity Questionnaire-Short Form (IPAQ-SF), and temporomandibular disorder severity with the Fonseca Anamnestic Index (FAI).

Results: There was no statistically significant difference in headache severity between individuals diagnosed with migraine and TTH (p>0.05). PPT measurement values of the trapezius and suboccipital muscles evaluated bilaterally did not show a statistically significant difference between the two groups (p>0.05). The average HIT-6 score of individuals diagnosed with migraine was found to be higher than individuals with TTH (p=0.003). The temporomandibular disorder severity level of individuals diagnosed with migraine was found to be higher than individuals diagnosed with TTH (p=0.002). There was no statistically significant difference between the groups in terms of physical activity level (p>0.05).

Conclusion: These findings highlight the importance of a holistic approach to headache management, addressing both primary symptoms and comorbid conditions, to improve patient outcomes. Determination of headache impact level and temporomandibular disorder severity in individuals with migraine and TTH may help physiotherapists to achieve optimal results, and may contribute to the development of proactive approaches to headache.

Key Words: Migraine, Tension-type headache, Physical activity, Pain, Temporomandibular joint

ÖZ

Amaç: Bu çalışmanın amacı migren ve gerilim tipi baş ağrısı (GTBA) olan bireyleri ağrı, fiziksel aktivite düzeyi ve temporomandibular bozukluk şiddeti açısından karşılaştırmaktır.

Yöntem: Çalışmaya katılan 18-45 yaş arasındaki bireyler (n=48) nörolog tarafından migren veya GTBA tanısı konularak iki gruba ayrıldı. Ağrı şiddeti Vizüel Analog Skalası (VAS) ile, baş ağrısı etki düzeyi Baş Ağrısı Etki Testi (HIT-6) ile, basınç-ağrı eşiği J-Tech Dijital Algometre cihazı ile, fiziksel aktivite düzeyi Uluslararası Fiziksel Aktivite Anketi-Kısa Form (UFAA-KF) ile ve temporomandibular bozukluk şiddeti Fonseca Anamnestik İndeksi (FAİ) ile değerlendirildi.

Bulgular: Migren ve GTBA tanısı konulan bireyler arasında baş ağrısı şiddetinde istatistiksel olarak anlamlı bir fark bulunmadı (p>0.05). Trapezius ve suboksipital kasların bilateral olarak değerlendirilen basınç-ağrı eşiği ölçüm değerleri iki grup arasında istatistiksel olarak anlamlı bir fark göstermedi (p>0.05). Migren tanısı konulan bireylerin ortalama HIT-6 skorunun GTBA tanısı konulan bireylerden daha yüksek olduğu bulundu (p=0.003). Migren tanısı konulan bireylerin temporomandibular bozukluk şiddeti düzeyinin GTBA tanısı konulan bireylerden daha yüksek olduğu bulundu (p=0,002). Fiziksel aktivite düzeyi açısından gruplar arasında istatistiksel olarak anlamlı bir fark yoktu (p>0.05).

Sonuç: Bu bulgular, hasta sonuçlarını iyileştirmek için hem birincil semptomları hem de komorbid durumları ele alan bütünsel bir baş ağrısı yönetimi yaklaşımının önemini vurgulamaktadır. Migren ve GTBA'lı bireylerde baş ağrısı etki düzeyinin ve temporomandibular bozukluk şiddetinin belirlenmesi, fizyoterapistlerin optimum sonuçlara ulaşmalarına yardımcı olabilir ve baş ağrısına yönelik proaktif yaklaşımların geliştirilmesine katkı sağlayabilir.

Anahtar Kelimeler: Migren, Gerilim tipi baş ağrısı, Fiziksel aktivite, Ağrı, Temporomandibular eklem

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***Corresponding author/Sorumlu yazar:** Karamanoglu Mehmetbey University, Vocational School of Health Services, Department of Therapy and Rehabilitation, Karaman, Türkiye

[5*]Email: akdamelike1996@hotmail.com, [1]Email: ozlem.sert@karatay.edu.tr,[2]Email: fztkamilyilmaz@hotmail.com, [3]Email: umit.yuzbasioglu@toros.edu.tr, [4]Email: busekilincfet@gmail.com, [6]Email: bahriye.horasanli@karatay.edu.tr

INTRODUCTION

Headache, which is among the most prevelant nervous system disorders and causes significant disability, is defined by the World Headache Association as a disease that can be seen at any age, causes high health care expenditures but can be cured with appropriate treatment [1]. According to the International Headache Classification, headaches consists of two types as primary and secondary [2]. Primary headache refers to headache that is not due to a disease or head trauma, while secondary headache develops secondary to different health problems such as tumors, infections, vascular diseases and sinusitis. Migraine and tension-type headache (TTHs) are included in the primary headache group [3]. The causes of migraine and TTHs, which are among the most common headache types globally, include personal, social and economic factors [4]. Headaches are ranked 6th among the leading causes of years lived with disability worldwide, and in comprehensive headache epidemiology studies conducted in our country, the prevalence of headache is reported to be 68% in women and 62% in men [5].

In individuals under 50 years of age, migraine is a recurrent primary headache characterized by neurological, gastrointestinal and autonomic changes and is among the top 10 causes of disability [6,7]. Disorders such as neck pain, depression, and anxiety that accompany migraine place migraine in a central position among the problems that cause disability. Cervical dysfunction frequently accompanies migraines, with pain signals traveling through upper cervical nerves even when no structural abnormalities are present in the neck. Sensory input from these nerves converges with the trigeminal nerve within the brainstem and interacts with secondary neurons in the upper cervical area. Additionally, some branches of the trigeminal nerve extend to neck muscles via the skull, suggesting that trigeminal pathways may contribute to neck pain associated with migraines [7].

TTH is a common neurological disorder characterised by mild to moderate recurrent bilateral headaches that are described as a 'hatband' pattern [8]. According to this pattern, pain may radiate to the forehead, posterior part of the head and neck. TTH has 3 different pathophysiological mechanisms: genetic, myofascial and central sensitisation and chronification involving altered pain modulation [9]. Pericranial muscle tenderness is a common symptom in individuals with TTH, suggesting the potential of myofascial tissues in the pathophysiology of TTH [10]. Studies show that people with chronic TTH experience greater tenderness in both pericranial muscles and tendon attachment sites compared to healthy controls [11,12]. Additionally, myofascial trigger points and hyperirritable spots, often linked to taut bands in muscles, may contribute to the condition. Therefore, it is emphasized that it may mimic the TTH pattern of muscular origin in the head, neck and shoulder regions [12].

The trigger point theory reports that the presence of trigger points is associated with headache in the neck and chewing muscles (upper trapezius, sternocleidomastoideus, suboccipitalis, masseter and temporalis) [13]. On the other hand, considering the close physiological, anatomical and biomechanical relationship between the temporomandibular joint (TMJ) and the cervical region, the weakness of the deep flexor muscle group suggests that it will lead to negative effects on the TMJ [14].

Regular physical activity is associated with lower prevalence of migraine and severity of non-migraine headaches [15,16]. A review of the literature found few studies examining the relationship between physical activity and headaches. Varkey et al. [15] identified sedantary behavior as a increase the risk for non-migraine headaches in people without pre-existing headaches and noted that those with headaches tend to be less active than headache-free individuals. Köseoglu et al. [17] emphasized the positive impact of exercise on migraines, particularly in patients with low baseline beta-endorphin levels. Beier et al. [18] revealed that physical inactivity is associated with poor quality of life (QoL) in individuals suffering from headaches. In addition, physical inactivity and non-compliance with World Health Organisation recommendations for physical activity (150-300 minutes of moderate-intensity aerobic physical activity or at least 75-150 minutes of high-intensity aerobic physical activity per week, or an equivalent combination of both) are reported to be associated with primary headaches [16].

As a result of the literature review considering myofascial mechanisms such as muscle tenderness and physiological stress, trigger point theory, physical activity, cervical-TMJ relationship, no study comparing individuals with migraine and TTH in terms of pain severity, physical activity level and temporomandibular disorder severity was found. The aim of this study was to investigate pain, physical activity level and temporomandibular disorder severity levels in individuals with migraine and TTH and compare the results. Our hypotheses are as follows:

- H_1: There is a difference in pain between individuals with migraine and TTH.
- H_2: There is a difference in physical activity levels between individuals with migraine and TTH.
- H_3: There is a difference in temporomandibular disorder levels between individuals with migraine and TTH.

METHOD

Study Design and Participants

This study, which has an observational and cross-sectional study design, was carried out in KTO Karatay University Physiotherapy and Rehabilitation Application Laboratory between January-October 2023. With a mean headache severity of 7.4 out of 10 and a standard deviation of 1.6 in individuals with migraine and a mean headache severity of 5.5 and a standard deviation of 2.2 in individuals with tension-type headache, the minimum sample size required to find a clinically significant difference with an effect size of 1.05, 90% power and 0.05 bias level was determined as at least 40 participants in total, with at least 20 participants per group [19].

Our study is a triple blind study. Participants were diagnosed with migraine or TTH by a neurologist (BH) who is an expert in the field. The evaluations were made by physiotherapists (BKÖ, MM) who are expert in the field. Identification and analysis of the data into the system was done by another researcher (ÜY). A triple blind trial means that participants, physiotherapists and data analyst do not have access to details of group assignment. This ensures that bias for or against the tested evaluations is very unlikely to occur.

Inclusion Criteria: Participants were divided into two groups by being diagnosed with migraine or TTH by a neurologist (BH). The age range of the participants was determined as 18-45 years, which is a period when the prevalence of both migraine and tension-type headache is high [20]. Individuals with headache were classified by a specialist neurologist (BH) as chronic migraine (headache more than 15 days a month, at least 8 days of which were migraine for the last 3 months) and chronic TTH (headache occurring daily or very frequently, lasting for hours to days or continuous, bilaterally located) according to the diagnostic criteria in the 3rd edition of the International Headache Classification (ICHD-3) established by the International Headache Society (IHS) [8].

Exclusion Criteria: Individuals with general joint damage affecting the head, neck and shoulder area and individuals who received radiotherapy to these body parts, individuals diagnosed with cervical disc herniation, radiculopathy and myelopathy, individuals with a history of congenital diseases, women during menstruation and pregnant women were excluded from the study.

Data Collection

Sociodemographic characteristics of the participants such as age, body weight, height, body mass index, gender and occupational status were recorded with the Assessment Form. Participants were evaluated by an expert neurologist within the study team and then diagnosed with

migraine or TTH. The intensity of pain was evaluated using the Visual Analogue Scale (VAS), while the Headache Impact Test (HIT-6) assessed how headaches affected participants. Physical activity levels were evaluated using International Physical Activity Questionnaire-Short Form (IPAQ-SF), and the Fonseca Anamnestic Index (FAI) was used to determine the severity of temporomandibular disorder. Lastly, the participants' Pressure-Pain Threshold (PPT) was measured using the J-Tech Algometer Device (J-Tech Medical, Salt Lake City, UT, USA), an objective assessment tool. The total evaluation time was 15 minutes and all evaluations were completed in one session.

Outcome Measures

Assessment of Pain Severity: VAS, a self-reported measure of pain, was used to measure pain intensity. VAS consists of a 10-centimeter line. At the left end of the scale is written "No pain (0 cm)" and at the right end is written "Worst pain (10 cm)". Participants were asked to mark their pain level on the line. The measurement from the left side, which is the starting point of the scale, to the participant's marks, was recorded in centimeters [21].

Evaluation of Headache Impact Level: HIT-6 evaluates different parameters such as pain, vitality, psychological distress, role, sociability, and cognitive functioning. 3 of the 6 questions in the test specifically evaluate the previous 4 weeks, and the other 3 questions do not specify any time interval. The scoring of the scale, which is a 5-point Likert type (Never:6 point, Rarely=8 point, Sometimes=10 point, Very often=11 point, Always=13 point), is obtained by summing the answers from six questions. The total score of the questionnaire, the Turkish validity and reliability study of which was performed by Dikmen et al. in migraine patients, varies between 36-78 and higher scores show increased negative effect level [22].

Evaluation of Pressure-Pain Threshold: The PPT was measured using the J-Tech Digital Algometer. This threshold refers to the minimum pressure needed for the sensation of pressure to be perceived as pain. It assesses the increase in increased mechanical sensitivity, especially in headache studies. After the upper part of the trapezius muscle (the midpoint between the C7 vertebra and the acromion) and the suboccipital regions of the participants were evaluated by palpation, tender points were detected and then these regions were marked. Vertical and direct pressure was applied to the painful point with the 1 cm^2 diameter head of the algometer. Participants were required to indicate the point at which the sensation of pressure changed from a pressure sensation to a painful sensation, and this value was then recorded as kilograms per square centimeter (kg/cm^2). Each area was measured three times, with a 30-second interval between measurements. The mean value of three measurements was recorded [23].

Evaluation of Physical Activity Level: The physical activity levels of the participants were evaluated with the Turkish version of the IPAQ-SF with 7 questions [24]. The short form was used in our study. IPAQ-SF inquires about the duration and frequency of activities performed over the past seven days. While the sitting question in the questionnaire is not included in the total score, scores for light, moderate and vigorous activities are calculated and the sum of 3 different physical activity levels gives the overall score. The total score of IPAQ-SF is obtained by multiplying the days, minutes, and Metabolic Equivalent of Task (MET) value. For its calculation, the formula Physical Activity Total Score (MET-min/week) = [(walking time×day×3.3 METs) +(moderate activity time×day×4 METs) +(vigorous activity time×day×8 METs)] was used (24). To calculate Physical Activity Total Score (MET-min/week) = [(Walking time×day×3.3 MET) + (Moderate activity time×day×4 MET) + (Vigorous activity time×day×8 MET)] formula was used [24].

Evaluation of Temporomandibular Joint Dysfunction Severity: The presence and degree of temporomandibular disorder were evaluated using the FAI. Turkish validity and reliability study was performed by Kaynak et al. The FAI consists of a total of 10 questions [25]. Each question in the index has 3 answer options as Yes: “10 points”, Sometimes: “5 points” and No: “0 points”. The increase in the total index score indicates an increase in the severity of temporomandibular disorder.

Ethical Approval

In this study, which had an observational and cross-sectional study design, the ethical criteria of the Declaration of Helsinki were followed and the participants were informed about the study in detail. Participants who have both verbal and written informed consent and signed the Informed Consent Form participated in the study. Ethical approval for the research was given by KTO Karatay University Pharmaceutical and Non-Medical Device Research Ethics Committee with decision number 2022/015.

Statistical Analysis

SPSS statistical software version 26 was used for statistical analysis of the data (Statistical Package for Social Science for Windows, Version 26.0, Inc, an IBM Company, Chicago, IL, USA). Demographic data were given as mean±standard deviation and percentage (%). The independent sample t-test was employed for data that exhibited a normal distribution, whereas the Mann-Whitney U test was utilised for data displaying a non-normal distribution.

RESULTS

The groups were similar in terms of age (p=0.900), height (p=0.462), body weight (p=0.845) and body mass index (p=0.863) (Table 1). The gender and occupational status of the individuals are shown in Table 1.

Table 1. Demographic characteristics of groups

Parameters	Migraineurs(n=24)	TTH (n=24)	t	p
Age (years)	24.29±6.89	24.04±6.85	0.126	0.900
Height (m)	1.66± 6.86	1.64±6.36	0.742	0.462
Body mass (kg)	64.70±13.76	63.95±12.72	0.196	0.845
BMI (kg/m^2)	23.35±4.29	23.57±4.64	-0.174	0.863
Sex (n/%)				
Male	2/8.3%	-		
Female	22/91.7%	24/100%		
Occupational Status				
Student	19/79.2%	18/75%		
Worker	3/12.4%	1/4.2%		
Academician	1/4.2%	3/12.4%		
Administrator	1/4.2%	2/8.4%		

BMI:Body mass index

The analyses revealed similar headache severity values between individuals with migraine and those with TTH (p>0.05). Similarly, the PPT values for the trapezius and suboccipital muscles, measured on both sides, showed no significant difference between the two groups (p>0.05) (Table 2).

The mean HIT-6 score of individuals diagnosed with migraine was found to be higher than individuals with TTH (p=0.003). In addition, the temporomandibular disorder severity level of individuals diagnosed with migraine was found to be higher than individuals diagnosed with tension-type headache (p=0.002). In terms of physical activity level no statistically significant difference was found between the groups (p>0.05) (Table 3).

Table 2. Comparison of headache severity and PPT values between groups

Parameters	Migraineurs (n=24)	TTH (n=24)	t	p
Headache pain intensity (VAS-cm)	5.63±2.35	5.56±1.52	0.125	0.901
PPT-M. Trapezius (right) (kg/cm^2)	55.19±18.03	52.03±15.84	0.646	0.521
PPT-M. Trapezius (left) (kg/cm^2)	50.92±15.61	45.90±13.83	1.178	0.245
PPT-M. Suboccipitalis (right) (kg/cm^2)	43.65±12.74	44.38±14.50	-0.186	0.853
PPT-M. Suboccipitalis (left) (kg/cm^2)	44.55±13.47	46.10±16.84	-0.353	0.726

*VAS-cm:Visual Analog Scale-centimeter; kg/cm^2:kilograms per square centimeter; M:Musculus; TTH:Tension-Type Headache; PPT:Pressure Pain Threshold; *p<0.05*

Table 3. Comparison of HIT-6, FAI and IPAQ-SF values between groups

Parameters	Migraineurs (n=24)	TTH (n=24)	t	p
HIT-6	67.45±5.11	62.41±5.99	3.135	0.003[a]*
FAI	50 (36.25-70)	35 (25-45)	3.269	0.002[b]*
IPAQ-SF	1219.75 (717.75-2725.50)	1328.25 (750.75-2178.50)	0.382	0.992[b]

*a:Independent samples t test; b:Mann Whitney U Test; TTH:Tension-Type Headache; HIT-6:Headache Impact Test-6; FAI:Fonseca Anamnestic Index; IPAQ-SF:International Physical Activity Questionnaire-Short Form; *p<0.05*

DISCUSSION

The purpose of the present study was to compare individuals with migraine and TTH in terms of physical activity level, pain and severity of temporomandibular disorder. In this context, no difference was found in terms of pain and physical activity in individuals with migraine and TTH; however, the severity of temporomandibular dysfunction was statistically significantly higher in individuals with migraine compared to individuals with TTH. According to these results, H1 and H2 were not supported but H3 was supported. The findings revealed some important insights into the differences and similarities between these two common types of headaches.

Our results, consistent with previous studies [26,27], showed similar values in headache severity between individuals diagnosed with migraine and individuals diagnosed with TTH. This suggests that although the nature and triggers of the pain may be different, the perceived severity of headaches may be comparable between the two groups. However, individuals with migraine reported a higher impact of their headaches on their daily lives, according to HIT-6 results. Similarly, Kim et al. [28] reported that more individuals with migraine (31.5%) were affected by headache than individuals with TTH (7%) (Headache Impact Level score ≥56). This suggests that migraine has a more profound impact on individuals' QoL than TTH due to associated symptoms such as nausea, photophobia, phonophobia.

In studies, PPT values measured on both the trapezius muscle and suboccipital muscles were found to be lower in individuals with migraine and chronic TTH compared to controls [29,30]. However, comparisons have also been made between different headache types. An interesting study reported that individuals with chronic TTH generally showed lower PPT values than both unilateral migraine patients and controls [31]. Similarly, Malo-Urries et al. [32] also stated that TTH exhibited lower PPT values compared to migraine, cluster headache and controls. On the other hand, Filatova et al. [33] reported that the mean PPT values in the neck region including the forehead, temple and the area between the trapezius muscle and C2 were similar between chronic temporomandibular disorder and chronic migraine. Additionally, no significant difference in PPT values in the neck region was identified in geriatric population with episodic TTH, migraine, cervicogenic headache, or unclassifiable headaches [34]. There may be various reasons why study results differ. The results may be affected by many factors such as the number of participants in the studies, differences between the methods and protocols used and measurement sites, the type, frequency, severity and duration of migraine, and whether the TTH is chronic or episodic. Present study shows that PPT values of the trapezius and suboccipital muscles were similar between groups. This result indicates that local muscle tenderness may not differ between migraine and TTH patients. This may mean that although the pain mechanisms and pathways involved in headaches are different, their peripheral reflections in terms of muscle sensitivity are comparable.

Previous studies have revealed that both migraine [35] and TTH [36] negatively affect physical activity level. Krøll et al. [37] reported that physical activity levels were lower especially in migraine patients, followed by individuals with temporomandibular disorder and neck pain. The results of a recent study conducted in Brazil with 14,088 participants showed that individuals with TTH (137.8±189.9 min/week) and migraine (109.9±165.9 min/week) had similar physical activity levels. In the present study, similar to the results of de Oliveira et al. [38] no significant difference was found between the groups in terms of physical activity levels. This may be because participants in both groups had similar lifestyle habits or because their physical activity levels could not be assessed with a more objective method and sensitive differences could not be detected. However, the lack of difference indicates that the complexity of headache problems has a multidimensional nature, including triggers and exacerbating factors.

Temporomandibular disorders are a common condition in individuals with headaches [39]. Temporomandibular disorder may aggravate headache symptoms or cause a primary headache disorder, the perception of pain in the masticatory muscles or TMJ [40]. In our study, the severity of temporomandibular disorder was found to be greater in individuals with migraine in comparison to participants with TTH. This finding is particularly interesting considering the anatomical and functional relationship between the TMJ and the cervical region. The recurrent and intense nature of migraine pain suggests that it may exacerbate or contribute to temporomandibular disorder, possibly through mechanisms involving muscle tension or trigeminal nerve involvement [7]. This supports the idea that comorbid conditions such as temporomandibular disorders are more frequently seen in individuals with migraine [39] and may contribute to their overall experience of disability and pain.

As a result of a comprehensive literature review, no study was found that evaluated and compared the PPT in the muscles around the neck of individuals with migraine and TTHs with objective measurement methods such as digital inclinometer. Moreover, our study is the first to investigate and compare the severity of temporomandibular disorder in migraine and TTH, which are among the primary headaches.

Limitations

There are certain limitations to this study, such as its cross-sectional design, which restricts the ability to draw causal conclusions, and its reliance on self-reported measures of physical activity level. Another limitation is that the PPT measurements focus only on neck muscles and that the masticatory muscles are not included in the assessments. Future research should aim to use longitudinal designs to investigate causal relationships between physical activity, headache intensity, and temporomandibular disorder. Additionally, objective measurements of physical activity level and more detailed assessments of headache-related disability may provide more comprehensive information.

CONCLUSION

In conclusion, this study enhances the insight of the complex interaction between headache types, physical activity, and temporomandibular disorder. While migraine and TTH share some similarities in terms of headache severity and muscle tenderness, they differ significantly in their effects on daily life and associated temporomandibular disorder. These findings emphasize the significance of a multidirectional to headache management, addressing both primary symptoms and comorbid conditions, to improve patient outcomes. It also suggests that encouraging exercise may be beneficial for all headache sufferers, not just those with migraine.

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EFFECTS OF BREATHING EXERCISES ON PAIN AND FUNCTIONALITY IN ROTATOR CUFF TEARS: A RANDOMIZED CONTROLLED TRIAL

ROTATOR CUFF YIRTIKLARINDA SOLUNUM EGZERSİZLERİNİN AĞRI VE FONKSİYONELLİK ÜZERİNE ETKİSİ: RANDOMİZE KONTROLLÜ ÇALIŞMA

Burak Menek[1*], Alper Ceylan[2], Umut İslam Tayboğa[2], Beyza Nur Erayata[2]

[1]Department of Physiotherapy and Rehabilitation, Faculty of Health Sciences, İstanbul Medipol University, İstanbul, Türkiye

[2]Department of Physiotherapy and Rehabilitation, Institute of Health Sciences, İstanbul Medipol University, İstanbul, Türkiye

ABSTRACT

Objective: Rotator cuff tears (RCT) were common shoulder injuries that caused pain, strength loss, and functional impairment. This study assessed the effectiveness of adding breathing exercises to conventional physiotherapy to alleviate pain and improve functionality in individuals with RCT.

Method: In this single-blind, randomized controlled trial, 30 participants aged 30–55 with diagnosed RCT were allocated into two groups: the Conventional Group (CG), receiving standard physiotherapy, and the Breathing Exercise Group (BEG), receiving standard physiotherapy plus breathing exercises for six weeks. Outcome measures included pain intensity assessed by the Numeric Pain Rating Scale (NRS), range of motion (ROM) measured with a goniometer, and shoulder functionality evaluated using the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire.

Results: Baseline demographic and clinical parameters did not differ significantly between groups ($p>0.05$). Both groups demonstrated significant improvements in pain, ROM, and DASH scores post-treatment ($p<0.05$). However, BEG showed superior improvements in nearly all outcomes, with statistically significant differences in NRS-activity, DASH scores, and ROM (flexion, abduction, internal and external rotation) compared to CG ($p<0.05$). No significant difference was observed in shoulder extension ROM between the groups.

Conclusion: The integration of breathing exercises into conventional physiotherapy significantly enhances pain relief and functional outcomes in individuals with RCT. These findings support the inclusion of breathing exercises as a complementary approach in conservative rehabilitation programs for rotator cuff injuries.

Key Words: Breathing exercises, Physiotherapy, Rehabilitation, Rotator cuff

ÖZ

Amaç: Rotator cuff yırtıkları (RCY) omuzda ağrı, kuvvet kaybı ve fonksiyonel kısıtlılıklara neden olan yaygın yaralanmalar arasında yer almaktadır. Bu çalışmada RCY'de ağrıyı azaltmak ve fonksiyonel yetenekleri geliştirmek amacıyla solunum egzersizlerinin konvansiyonel fizyoterapiyle kombinasyonunun etkinliğinin incelenmesi amaçlandı.

Yöntem: Bu randomize ve tek kör çalışmada, 30-55 yaşları arasında RCY tanısı almış 30 birey yer aldı. Katılımcılar altı hafta boyunca rutin fizyoterapi uygulanan Konvansiyonel Grup (KG) ve aynı programa ek olarak solunum egzersizleri uygulanan Solunum Egzersizi Grubu'na (SEG) ayrıldı. Ağrı, Sayısal Ağrı Derecelendirme Ölçeği (NRS) ile ölçülürken; eklem hareket açıklığı (ROM) gonyometre ile, omuz fonksiyonelliği ise Kol, Omuz ve El Yetersizlik Anketi (DASH) ile değerlendirildi.

Bulgular: Tedavi öncesi gruplar arasında demografik özellikler ve temel ölçümler açısından anlamlı bir fark bulunmadı ($p>0.05$). Tedavi sonrasında her iki grupta da tüm parametrelerde iyileşme gözlendi ($p<0.05$). SEG, NRS-aktivite, DASH skoru ve Eklem Hareket Açıklığı (fleksiyon, abdüksiyon, internal ve eksternal rotasyon) açısından KG' ye kıyasla istatistiksel olarak daha etkiliydi ($p<0.05$). Bununla birlikte, omuz ekstansiyonu hareket açıklığı açısından gruplar arasında istatistiksel olarak anlamlı bir fark saptanmadı; her iki grubun tedavi sonrası değerleri benzer düzeyde kaldı ($p>0.05$).

Sonuç: Solunum egzersizlerinin konvansiyonel fizyoterapiye eklenmesinin RCY tedavisinde ek faydalar sağladığı gözlendi. Bulgular, RCY tedavi protokollerine solunum egzersizlerinin dahil edilmesinin ağrı yönetimi ve fonksiyonel iyileşmeyi artırabileceğini gösterdi.

Anahtar Kelimeler: Solunum egzersizleri, Fizyoterapi, Rehabilitasyon, Rotator cuff

INTRODUCTION

Shoulder pain is a prevalent musculoskeletal condition affecting a significant portion of the population. Studies have shown that the annual prevalence of shoulder pain is approximately 47%, while the lifetime prevalence can reach up to 70% [1]. Rotator cuff tear (RCT) is a prevalent condition frequently leading to shoulder pain and impairing functionality in various daily activities. This syndrome induces pain and disability among affected individuals [2]. Rotator cuff tears are prevalent in individuals aged 40-60 and show a significant increase with age. According to the study by Yamamoto et al., rotator cuff tears were identified in 6.7% of individuals in their 40s and 12.8% of individuals in their 50s. This study examined the prevalence of rotator cuff tears in general population and found a trend of increasing prevalence with age [3,4]. RCTs are distinguished by symptoms such as shoulder pain, restricted range of motion, weakened shoulder muscles, and impaired function [5,6]. Numerous studies have beenconducted on the efficacy of surgical and conservative treatment

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***Corresponding author/Sorumlu yazar:** İstanbul Medipol University, Faculty of Health Sciences, Department of Physiotherapy and Rehabilitation, İstanbul, Türkiye
[1*]Email: bmenek@medipol.edu.tr, [2]Email: alper.ceylan@medipol.edu.tr, [3]Email: umut.tayboga@medipol.edu.tr, [4]Email: beyza.erayata@medipol.edu.tr

methods for rotator cuff tears; however, conservative treatment is generally recommended as the first choice, particularly for non-traumatic tears [7,8]. In managing rotator cuff tears, conservative treatment options encompass a range of interventions such as exercises to improve range of motion (ROM), stretching, strengthening, and mobilization [9,10]. The primary objectives of conservative treatment are to alleviate pain, enhance muscle strength, and restore ROM [9]. In recent years, there has been growing interest in using breathing exercises as a therapeutic intervention for pain management and musculoskeletal disorders [11,12]. Studies on the positive effects of breathing exercises on pain management have shown that these exercises modify pain management have shown that these exercises modify pain perception and improve body alignment. Diaphragmatic breathing reduces pain perception by decreasing sympathetic nervous system activity and alleviating muscle tension, thereby improving posture [13,14]. The activation of the diaphragm has been found to alter the perception of pain and promote proper posture and body alignment, thereby contributing to overall well-being [15]. Evidence suggests that doing yoga with breathing exercises has the potential to reduce pro-inflammatory markers, indicating their effectiveness in mitigating inflammation [16,17]. Research has shown that breathing exercises reduce pain and improve quality of life and range of motion. It has been emphasized that diaphragm activation benefits body mechanics, particularly in musculoskeletal disorders [18]. In the study by Fernández-López et al., three different intervention methods, manual diaphragm therapy, myofascial trigger point treatment, and active diaphragm mobilization, were compared to evaluate the immediate effects on shoulder pain and mobility [19]. Our study focuses on the integration of breathing exercises into conventional physiotherapy, examining the long-term effects of reducing pain and improving functionality in rotator cuff tears. Unlike the study by Fernández-López et al., which assessed immediate effects, our study evaluates longer-term outcomes. Additionally, while their study compared three different intervention groups, our study investigates the effectiveness of combining breathing exercises with conventional physiotherapy. Although the study by Fernández-López et al. makes significant contributions to the literature, our study aims to address the gap by exploring the long-term therapeutic benefits of breathing exercises in rotator cuff tears, thereby providing a unique perspective and practical insights for clinical applications. The activation of the diaphragm has been shown to influence pain perception and enhance shoulder joint functionality. While previous studies have primarily focused on the isolated effects of breathing exercises on pain, posture, and the musculoskeletal system, limited research has explored their integration with conventional physiotherapy for individuals with rotator cuff tears (RCT). This study investigates the combined effects of breathing exercises and physiotherapy on pain reduction, improved range of motion (ROM), and enhanced shoulder functionality. It hypothesizes that incorporating breathing exercises into conventional therapy may yield superior outcomes compared to conventional interventions alone. By evaluating this integrated approach, the study aims to provide new insights into the role of breathing exercises in RCT rehabilitation, particularly their potential to improve pain management and functional recovery.

METHOD

Study Design

This randomized controlled trial utilized a single-blind design, with participants randomly allocated to one of two groups in a 1:1 ratio. A total of 30 individuals who fulfilled the eligibility criteria for the RCT were enrolled in the study. All participants received comprehensive information about the study and provided written informed consent. A total of 42 individuals were initially screened for participation. Seven individuals were excluded due to not meeting the inclusion criteria, and five declined to take part. Consequently, the final sample included 30 participants who were randomly assigned to one of two groups. In the Breathing Exercise Group (BEG), there were six males and nine females, and in the Conventional Group (CG), there were five males and 10 females.

Participants were sequentially numbered from 1 to 30 based on the order of their arrival at the clinic. These numbers were randomized using the randomization algorithm on the "randomizer.org" website to ensure homogeneous distribution among groups and minimize potential confounding factors. According to the randomized sequence, participants were assigned to either the CG (n=15) or BEG (n=15). The randomization process was conducted immediately after participants were enrolled in the study. To ensure blinding, all participants were provided with standardized information regarding the general benefits of the exercises, while group-specific details were not disclosed. This approach created the impression that both groups followed similar protocols, thus maintaining neutrality.

Participants

Thirty participants with a physician-confirmed partial tear of the supraspinatus at Istanbul Medipol University Hospital, who met the inclusion criteria, were recruited for this study. The participants were between the ages of 30 and 55, had no history of shoulder surgery, exhibited restricted shoulder joint range of motion, and had a diagnosed rotator cuff tear. The exclusion criteria were as follows: individuals with a history of significant shoulder trauma, anatomical deformities, skeletal fractures, diagnosed orthopedic or rheumatologic disorders, participation in a physiotherapy program within the last six months, presence of a cardiac pacemaker, current infections, recent myocardial infarction (within the last six months), or any other condition that could interfere with their ability to perform the prescribed exercises. The study's progress and participant flow are illustrated in the Consolidated Standards of Reporting Trials (CONSORT) flow diagram (Fig. 1).

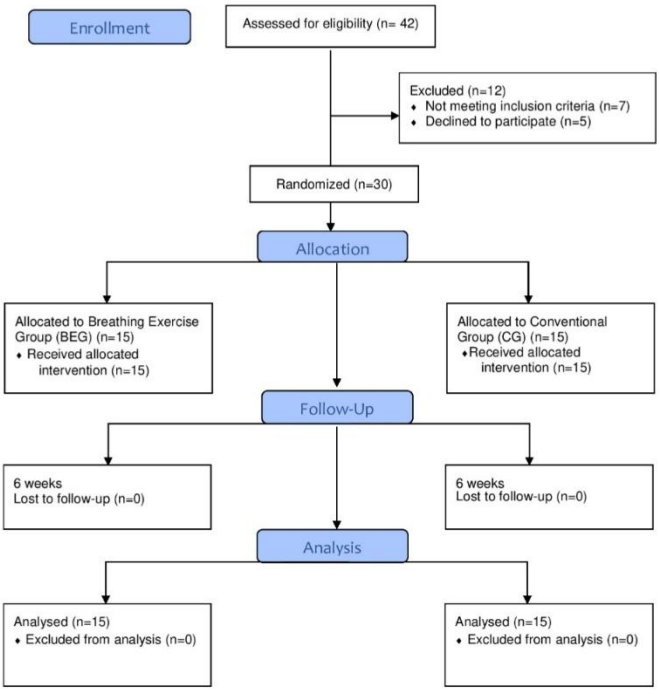

Figure 1. Design and flow of participants through the trial

Intervention

Conventional Group

In addition to standard physiotherapy techniques, a range of therapeutic modalities and exercises were used to treat the affected shoulder. These included cold pack application, ultrasound therapy, transcutaneous electrical nerve stimulation (TENS), finger ladder exercises, Codman exercises, shoulder wheel exercises, and wand

exercises. The wand exercises were performed in both directions, with ten repetitions each, while the Codman exercises were completed with 30 repetitions in each direction. Ultrasound therapy was administered to the affected shoulder daily for six minutes per session, five days a week, over a total of 30 sessions. The ultrasound intensity was set at 1.5 W/cm², ensuring full contact with the shoulder area at a perpendicular angle. Manual stretching was conducted by the physiotherapist, targeting shoulder flexion, abduction, extension, external rotation, and internal rotation. These stretches were performed five times in each direction, with each stretch held for 20 seconds. TENS was applied for 20 minutes at a frequency of 100 Hz, and a cold pack was applied to the shoulder for 15 minutes [5,9]. All conservative interventions were conducted under the supervision of a physiotherapist five days a week for six weeks. An individualized exercise progression plan was designed for each participant based on their response to the treatment protocol. The progression framework involved gradually increasing the number of repetitions and the difficulty level of the exercises, ensuring an appropriate and stepwise increase in intensity tailored to each participant's individual capacity.

Breathing Exercises Group

In addition to conventional physiotherapy, diaphragmatic breathing, and thoracic expansion, breathing exercises were performed five days a week under the supervision of a physiotherapist.

Diaphragmatic Breathing Exercises Protocol

1. Participants assumed a supine position on a flat surface or bed with knees bent. A pillow was utilized, if desired, to provide support for the head and knees, enhancing comfort
2. One hand was placed on the upper chest area, while the other was positioned just below the rib cage on the abdomen.
3. Participants were instructed to inhale slowly through the nostrils, allowing the air to penetrate the lower abdomen deeply. While the hand on the chest remained stationary, the hand on the abdomen was raised.
4. Abdominal muscles were contracted, and participants were allowed to draw them inward during exhalation through pursed lips. The hand on the abdomen was returned to its initial position [20].

Thoracic Expansion Protocol

In a seated or standing posture, the individual was directed to inhale deeply while raising both arms and retain their breath for 2-3 seconds. Participants were then instructed to exhale while lowering their arms. Following this, they were asked to fully adduct their shoulders, take a deep breath, hold it for 2-3 seconds, and then exhale. Next, they were directed to take a deep breath while raising one shoulder, holding it for 2-3 seconds, and exhaling as they lowered the elevated shoulder, repeating the process with the other shoulder. This sequence was performed five times during each exercise session [21].

Outcome Measures

All individuals' demographic information was recorded before the study. Before the application, the shoulder functionality of all individuals was evaluated with a Numerical Rating Scale (NRS), goniometric measurement, and The Disabilities of the Arm, Shoulder, and Hand Questionnaire (DASH). After the first evaluation, applications were made to the participants according to the groups they were interested in, and then the first evaluation methods were repeated.

Primary Outcome

The Numeric Rating Scale (NRS): NRS is commonly employed in both research and clinical environments to quantify the level of pain experienced by individuals [22]. In pain assessment, the absence of pain is commonly denoted as a numerical value of 0, while the most severe pain level is represented by a value of 10 [23].

Secondary Outcomes

Range of Motion: A universal goniometer was utilized to assess the range of motion in the affected shoulder for flexion, extension, abduction, as well as internal and external rotation. The reference values applied for these measurements were 45 degrees for extension, 0-180 degrees for flexion and abduction, and 0-90 degrees for both internal and external rotation [24].

The Disabilities of the Arm, Shoulder, and Hand (DASH): The DASH scale, created by the American Academy of Orthopedic Surgeons in collaboration with other professional organizations, is a standardized instrument used to evaluate physical limitations and functional impairments in individuals with upper extremity conditions. The DASH questionnaire includes three distinct subdomains. The first section consists of 30 questions, with 21 items focusing on the patient's difficulties in performing daily activities, five items assessing symptoms, and the remaining four items addressing social functioning, work productivity, sleep quality, and self-confidence. Higher scores on the DASH questionnaire indicate greater levels of disability and functional limitation, whereas lower scores reflect less disability and better functional status [25].

Ethical Approval

The trial adhered to the ethical principles outlined in the Declaration of Helsinki. The study protocol was approved by the Non-Interventional Ethics Committee of Istanbul Medipol University (date: 25.08.2022, approval number: 742). Additionally, the protocol was registered with ClinicalTrials.gov (NCT05584345).

Statistical Analysis

The required sample size for the study was calculated to be 30 participants, providing 80% statistical power (α=0.05) with an effect size of 0.80, particularly for the pain assessment. This calculation was performed using G*Power software (version 3.1.9.2) [26]. The data were analyzed using IBM SPSS Statistics Standard Concurrent User Version 26 (IBM Corp., Armonk, New York, USA). Descriptive statistics were presented as frequency (n), percentage (%), mean ($\bar{X}$), standard deviation (SD), median (M), minimum (min), and maximum (max) values. The Shapiro-Wilk test was applied to check the normality of the numerical data distribution. To compare numerical characteristics between groups, the Independent Samples t-test was used, while categorical data were compared using chi-square tests (either Pearson chi-square or Fisher's exact test). Within-group changes in the dependent variables before and after the intervention were assessed using paired samples t-tests, and between-group differences were examined with independent samples t-tests. A mixed-design analysis of variance (ANOVA) was performed to compare variables across different time points within each group. Effect sizes were reported as partial eta-squared (η^2p), with thresholds of 0.01 for small, 0.06 for medium, and 0.14 for large effects, according to Cohen's d [27]. A p-value of less than 0.05 was considered statistically significant for all analyses.

RESULTS

The demographic and clinical characteristics of the participants, including age, height, gender, and symptom duration, were similar between the Conventional Group (CG) and the Breathing Exercise Group (BEG), as summarized in Table 1. Table 2 presents the pre-and post-treatment comparisons for each group, as well as the differences between the groups. Both groups demonstrated significant improvements in NRS scores (at rest and during activity), DASH scores, and ROM parameters after treatment ($p<0.05$). However, the BEG group exhibited more pronounced improvements across all parameters compared to the CG group, with a significance level of $p<0.01$. For NRS-Resting, the BEG group achieved a larger reduction in scores (mean difference:-4.93±1.87, η^2=0.844) compared to the CG group (-3.20±1.15, η^2=0.695). Similarly, NRS-Activity scores decreased significantly in the BEG group (mean difference:-6.4 ±1.40,

η^2=0.943) compared to the CG group (-3.60±0.83, η^2=0.839). DASH scores also showed greater improvement in the BEG group (mean difference:-62.28±11.75, η^2=0.954) than in the CG group (-37.56±8.00, η^2=0.882). Regarding ROM, the BEG group demonstrated substantial improvements in flexion, abduction, and internal and external rotation parameters. For example, ROM-Flexion increased significantly in the BEG group (mean difference: 69.27±17.82, η^2=0.919) compared to the CG group (41.93±11.76, η^2=0.805). ROM-Abduction improvements were also more notable in the BEG group (mean difference: 72.67±23.67, η^2=0.871) than in the CG group (48.27±16.76, η^2=0.748). For ROM-Internal Rotation, the BEG group achieved greater gains (mean difference: 46.33±11.72, η^2=0.902) than the CG group (24.13±10.62, η^2=0.714).

Table 1. Baseline characteristics of the participants

Baseline Characteristics	**Group**		**Test (*p*)**
	CG ***n*=15**	**BEG** ***n*=15**	
Age, (*years*)			
X±*SD*	44.60±6.99	45.73±8.31	*t*=-0.404
M (*min-max*)	47 (31-53)	49 (30-55)	*(*0.689)
Gender, *n* (*%*)			
Male	5 (%33)	6 (%40)	χ^2=0.144
Female	10 (%67)	9 (%60)	*(*0.705)
Height, (*cm*)			
X±*SD*	166.73±6.56	166.00±8.54	*t*=0.264
M (*min-max*)	165 (155-175)	165 (155-183)	*(*0.794)
Weight, (*kg*)			
X±*SD*	72.00±6.27	75.93±9.66	*t*=-1.323
M (*min-max*)	74 (60-85)	73 (60-90)	*(*0.197)
Body Mass Index, (kg/m^2)			
X±*SD*	25.97±2.68	27.75±4.44	*t*=-1.326
M (*min-max*)	25.6 (21.6-32.4)	27.7 (21.2-35.2)	*(*0.195)
Affected Side, *n* (*%*)			
Right	9 (%60)	9 (%60)	χ^2=0.001
Left	6 (%40)	6 (%40)	*(*0.999)
Time of onset of symptoms, (*weeks*)			
X±*SD*	2.73±1.22	3.07±1.75	*t*=-0.604
M (*min-max*)	2 (1-5)	3 (1-6)	*(*0.550)

CG:Conventional Group; BEG:Breathing Exercise Group; SD:Standard Deviation

DISCUSSION

In our study, significant pain, functionality, and ROM improvements were observed in both the conventional and breathing exercise groups. However, the breathing exercise group demonstrated superior outcomes across all measures. This suggests incorporating breathing exercises into conventional treatment may enhance therapeutic outcomes in individuals with rotator cuff tears.

Conservative physiotherapy approaches are considered the first treatment approach for shoulder pain in individuals with rotator cuff tears. Physiotherapy approaches aim to relieve pain by reducing muscle spasms and increasing soft tissue mobilization. Furthermore, physiotherapy interventions increase functionality by increasing ROM and strengthening muscles [28].

A meta-analysis study conducted in 2017 compared the effectiveness of surgical and conservative treatment in individuals with rotator cuff tears. It showed that surgical treatment was not more effective than conservative treatment alone [29]. In a study by Kukkonen et al., it was shown that surgical and conservative treatment is effective in reducing pain in individuals with rotator cuff tears [30]. In research, the effectiveness of surgical and conservative treatment on pain, muscle strength, and functionality in individuals with rotator cuff tear was examined, and as a result of the study, it was reported that although surgical treatment gave better results than conservative treatment, the differences were very small and not clinically significant [8]. In the case of a study investigating the effectiveness of surgical and conservative treatment on pain, functionality, and disability in individuals with a rotator cuff tear, no difference was observed between the effectiveness of both treatments on functionality. Although surgical treatment gave better results on pain and disability, the authors reported that the difference between the results was very small [31]. These literature findings demonstrate that conservative physiotherapy approaches are an effective treatment option for rotator cuff tears and can provide similar outcomes compared to surgical treatment. In our study, the conventional therapeutic interventions applied also yielded significant improvements in pain, range of motion, and functionality parameters in individuals.

In a study in which patients with RC tendinopathy were treated with conventional exercise therapy, they were evaluated with the Constant Murley questionnaire, which included pain, daily living movements, range of motion, and strength parameters, in addition to the VAS for pain in daily life. As a result of the study, significant improvements were seen in both the Constant Murley score and VAS parameters [28]. A study conducted with 46 adults suffering from rotator cuff tears demonstrated that a structured rehabilitation program targeting the deltoid muscle, combined with electromyographic biofeedback, yielded positive outcomes in conservative treatment by improving shoulder flexion strength and enhancing patient satisfaction [32]. In a study comparing different exercise approaches after RC repair, both groups indicated significant improvements in all outcomes (DASH, pain, ROM, and strength) during the follow-up period [33]. It has been observed that shoulder functionality and pain are positively affected in patients with supraspinatus tendon rupture to whom electrotherapy modalities are applied [34]. Although significant improvements in ROM-Extension were observed within both groups after the intervention, the lack of a statistically significant difference between the groups may be attributed to the fact that extension movement is not as intensively utilized in daily activities as other planes of motion. This limitation could have resulted in a more restricted effect of the intervention on this specific motion plane, warranting further investigation in future studies. In our study, when we examined CG, in which electrotherapy modalities and therapeutic exercises were applied, we observed significant improvements in pain, functionality, and ROM parameters after treatment, similar to the results of studies in the literature.

Breathing exercises are known to be effective in sympathetic regulation and pain reduction [35]. Moreover, it has been suggested that vagal activity increases during breathing exercises, and thus, pain decreases [12]. It is recognized that respiratory exercises play a significant role in alleviating muscular tension in individuals experiencing pain [35]. In a study, breathing exercises were shown to be effective in increasing shoulder flexibility and decreasing shoulder pain in middle-aged female patients [12]. A different study suggested that breathing exercises may be effective in alleviating shoulder pain in patients undergoing laparoscopic cholecystectomy [36]. As a result of a case study in which the combination of PNF and deep breathing exercises was applied, a decrease in pain level and an increase in ROM values were observed [11]. In a separate study, indirect treatment of the shoulder using a protocol of manual therapy techniques targeting the diaphragm was found to be clinically effective in improving shoulder flexion and abduction movements [37]. A systematic review study revealed that manual diaphragm therapy showed a significant immediate effect on parameters related to rib, spine, and posterior muscle chain mobility [38]. Jafari et al. observed that hypoalgesia was more significant when breathing occurred at a slower frequency with a lower inspiration-to-expiration ratio [12]. Diaphragmatic breathing

naturally stimulates the vagus nerve, leading to the suppression of peripheral inflammatory cytokine release, lowering sympathetic activity, activating the parasympathetic nervous system, and aiding in pain management [39]. Thoracic expansion exercises, as a specific type of breathing exercise, also play a critical role in improving musculoskeletal function. These exercises promote thoracic mobility, enhance lung capacity, and improve postural alignment, which may reduce compensatory movements during shoulder rehabilitation. By improving thoracic flexibility, they can facilitate more effective biomechanical movement patterns in the shoulder girdle, reducing pain and enhancing functionality [21].

Table 2. Intra-group differences of values pre-treatment and post-treatment and comparison of differences between groups

Variables	Group		Test Statistics	Group	Time	Group X Time	Power (%)
	CG *n*=15	BEG *n*=15					
NRS-Resting							
Pre-test	5.87 ± 1.77	5.20 ± 1.86	F=1.013 p=0.323 η2=0.035	**F=12.869**	**F=206.313**	**F=9.370**	
Post-test	2.67 ± 1.05	0.27 ± 0.46	**F=66.219 p<0.001 η2=0.703**	**p=0.001**	**p<0.001**	**p=0.005**	**84.0%**
Mean difference	-3.20 ± 1.15	-4.93 ± 1.87		**η2=0.315**	**η2=0.881**	**η2=0.251**	
Test Statistics ϕ	**p<0.001 η2=0.695**	**p<0.001 η2=0.844**					
NRS-Activity							
Pre-test	8.27 ± 0.88	8.73 ± 0.88	F=2.091 p=0.159 η2=0.070	**F=12.223**	**F=564.516**	**F=44.258**	
Post-test	4.67 ± 0.82	2.33 ± 1.11	**F=42.875 p<0.001 η2=0.605**	**p=0.002**	**p<0.001**	**p<0.001**	**99.9%**
Mean difference	-3.60 ± 0.83	-6.40 ± 1.40		**η2=0.304**	**η2=0.953**	**η2=0.613**	
Test Statistics ϕ	**p<0.001 η2=0.839**	**p<0.001 η2=0.943**					
DASH							
Pre-test	74.44 ± 11.74	74.83 ± 12.26	F=0.008 p=0.930 η2=0.001	**F=14.658**	**F=740.324**	**F=45.393**	
Post-test	36.89 ± 8.81	12.55 ± 5.36	**F=83.526 p<0.001 η2=0.749**	**p<0.001**	**p<0.001**	**p<0.001**	**99.9%**
Mean difference	-37.56 ± 8.00	-62.28 ± 11.75		**η2=0.344**	**η2=0.964**	**η2=0.618**	
Test Statistics ϕ	**p<0.001 η2=0.882**	**p<0.001 η2=0.954**					
ROM-Flexion							
Pre-test	102.40 ± 14.86	105.07 ± 19.17	F=0.181 p=0.673 η2=0.006	**F=14.981**	**F=407.021**	**F=24.592**	
Post-test	144.33 ± 9.61	174.33 ± 9.04	**F=77.565 p<0.001 η2=0.735**	**p<0.001**	**p<0.001**	**p<0.001**	**99.8%**
Mean difference	41.93 ± 11.76	69.27 ± 17.82		**η2=0.349**	**η2=0.936**	**η2=0.468**	
Test Statistics ϕ	**p<0.001 η2=0.805**	**p<0.001 η2=0.919**					
ROM-Extension							
Pre-test	24.00 ± 11.83	31.00 ± 11.68	F=2.659 p=0.114 η2=0.087	**F=9.685**	**F=48.445**	F=0.736	
Post-test	34.67 ± 6.11	44.67 ± 1.29	**F=38.415 p<0.001 η2=0.578**	**p=0.004**	**p<0.001**	p=0.398	13.2%
Mean difference	10.67 ± 7.76	13.67 ± 11.09		**η2=0.257**	**η2=0.634**	η2=0.026	
Test Statistics ϕ	**p<0.001 η2=0.399**	**p<0.001 η2=0.522**					
ROM-Abduction							
Pre-test	82.07 ± 19.29	94.00 ± 21.06	F=2.619 p=0.117 η2=0.086	**F=19.793**	**F=260.842**	**F=10.619**	
Post-test	130.33 ± 17.21	166.67 ± 13.84	**F=40.597 p<0.001 η2=0.592**	**p<0.001**	**p<0.001**	**p=0.003**	**88.2%**
Mean difference	48.27 ± 16.76	72.67 ± 23.67		**η2=0.414**	**η2=0.903**	**η2=0.275**	
Test Statistics ϕ	**p<0.001 η2=0.748**	**p<0.001 η2=0.871**					
ROM-ER							
Pre-test	33.00 ± 18.69	42.33 ± 22.82	F=1.502 p=0.231 η2=0.051	**F=8.305**	**F=120.024**	**F=5.626**	
Post-test	58.33 ± 15.89	81.67 ± 10.12	**F=23.02 p<0.001 η2=0.451**	**p=0.008**	**p<0.001**	**p=0.025**	**62.9%**
Mean difference	25.33 ± 14.20	39.33 ± 17.92		**η2=0.229**	**η2=0.811**	**η2=0.167**	
Test Statistics ϕ	**p<0.001 η2=0.568**	**p<0.001 η2=0.760**					
ROM-IR							
Pre-test	34.33 ± 11.47	35.67 ± 9.23	F=0,123 p=0,728 η2=0,004	**F=12.883**	**F=297.842**	**F=29.561**	
Post-test	58.47 ± 14.05	82.00 ± 8.41	**F=30.983 p<0.001 η2=0.525**	**p=0.001**	**p<0.001**	**p<0.001**	**99.9%**
Mean difference	24.13 ± 10.62	46.33 ± 11.72		**η2=0.315**	**η2=0.914**	**η2=0.514**	
Test Statistics ϕ	**p<0.001 η2=0.714**	**p<0.001 η2=0.902**					

CG:Conventional Group; BEG:Breathing Exercise Grou;, NRS:Numerical Rating Scale; DASH:The Disabilities of the Arm Shoulder and Hand Questionnaire; ROM:Range of Motion; ER:External Rotation; IR:Internal rotation; F:Assesses the significance of differences between group; p<0.05 indicates statistical significance; η²:Represents effect size (0.01 small, 0.06 medium, 0.14 large), ANOVA test was used to evaluate differences between groups.

In a study by Fernández-López et al., the immediate effects of diaphragm manual therapy, myofascial trigger point treatment, and active diaphragm mobilization on shoulder pain and mobility were compared, showing improvements in pain levels and range of motion (ROM) [19]. However, these effects were evaluated in the short term without focusing on sustained outcomes.

In contrast, our study assessed the integration of breathing exercises with conventional physiotherapy over a longer duration of six weeks, examining their impact on pain, functionality, and ROM in individuals with rotator cuff tears. While Fernández-López et al. emphasized immediate post-intervention changes, our findings highlight the extended therapeutic benefits of breathing exercises, suggesting their role in not only reducing pain but also enhancing functionality and long-term rehabilitation outcomes. This comparative approach underscores the novelty of our study in addressing sustained effects and practical applications of breathing exercises within a broader treatment framework for rotator cuff injuries. We propose that breathing retraining exercises lower the respiratory rate, correct dysfunctional breathing patterns, and normalize respiratory chemistry (by increasing end-tidal CO2, restoring pH balance, and enhancing tissue oxygenation). This, in turn, reduces the excitability of the nervous and muscular systems, leading to analgesic effects [40]. Breathing exercises regulate the autonomic nervous system and exert direct biomechanical effects on core stability. Improved core stability and diaphragmatic control can reduce compensatory movements during shoulder rehabilitation, leading to more efficient movement patterns and decreased pain. In our study, we suggest that the superior outcomes observed in participants who received breathing exercises could be due to the analgesic effect induced by these exercises, which in turn led to an increased range of motion and improved functionality. It is well-established that breathing exercises alleviate pain perception through relaxation mechanisms. Furthermore, considering the anatomical and physiological connections between the diaphragm and shoulder via innervation and myofascial tissue, these exercises may directly influence shoulder function [19]. One of the key strengths of our study is the innovative application of breathing exercises in the context of rotator cuff tears. This area has been under-researched in literature. We suggest that incorporating breathing exercises into the rehabilitation program for rotator cuff tears, alongside traditional musculoskeletal approaches, could be effective, and we recommend that further research be conducted in this area.

Limitations

The limitations of our study include the inclusion of individuals with partial tears of the supraspinatus muscle; however, no grouping or classification was performed based on the tear size, which may have influenced the results. Additionally, the absence of a control group that did not receive any exercise intervention makes it challenging to isolate the specific effects of the treatments. Future studies are recommended to investigate long-term outcomes (e.g., beyond 12 weeks) for a more comprehensive understanding.

CONCLUSION

In conclusion, conventional treatment and breathing exercises are effective options for individuals with rotator cuff tears. Breathing exercises have more advantages in improving pain, ROM, and shoulder functionality than conventional treatment. Given the potential of breathing exercises to improve pain and functionality, clinicians may consider incorporating these exercises into standard rehabilitation protocols for rotator cuff tears.

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THE EFFECTIVENESS OF NURSE-LED TELENAVIGATION PROGRAM FOR PATIENTS WITH COLORECTAL CANCER: A RANDOMISED CONTROLLED TRIAL

KOLOREKTAL KANSERLİ HASTALARDA HEMŞİRE LİDERLİĞİNDEKİ TELENAVİGASYON PROGRAMININ ETKİNLİĞİ: RANDOMİZE KONTROLLÜ BİR ÇALIŞMA

Zeynep Çalı[1*], Elif Dönmez[2]

[1]Chemotherapy Unit, Avrasya Hospital, İstanbul, Türkiye

[2]Department of Oncology Nursing, Hamidiye Faculty of Nursing, University of Health Sciences, İstanbul, Türkiye

ABSTRACT

Objective: Telenavigation is a new and innovative cancer follow-up method for oncology nurses. Since the COVID-19 pandemic, the need for telemedicine in oncology has grown, alongside the integration of patient navigation services into telemedicine. However, studies on this topic remain limited. This study aims to evaluate the effect of a nurse-led telenavigation program on symptom management and psychosocial adjustment in colorectal cancer (CRC) patients.

Method: This randomized controlled study included 60 CRC patients divided into navigated and non-navigated groups through random allocation at a cancer center in Istanbul. The navigated group received a Nurse-led Telenavigation Program (NTP) through three sessions on WhatsApp, focusing on symptom management and psychosocial adjustment. Data were analyzed using statistical methods.

Results: The study examining the effects of a nurse-led telenavigation program (NTP) on patients with colorectal cancer (CRC) found that both the intervention (navigated) and control (non-navigated) groups experienced significant reductions in the physical and psychological well-being subscales, as well as the total scores of the N-SAS ($p<.05$). However, no significant differences were observed between the two groups in terms of N-SAS subscales or total scores ($p>.05$). In contrast, the navigated group showed a significant decrease in total PAIS-SR scores over time ($p<.05$), whereas the non-navigated group showed no significant change ($p>.05$). These findings suggest that the NTP significantly improved psychosocial adjustment in CRC patients ($p<.05$), although it had limited effectiveness in alleviating physical symptoms ($p>.05$).

Conclusion: In consideration of the fact that nurse navigation programs are disability-focused interventions tailored to cancer patients, the present study provides valuable guidance for oncology nurses aiming to improve the psychosocial well-being of colorectal cancer patients. Consequently, it is recommended that the nurse-led telenavigation program be further evaluated through additional studies involving more diverse populations and larger sample sizes.

Key Words: Colorectal cancer, Patient navigation, Telemedicine

ÖZ

Amaç: Telenavigasyon, onkoloji hemşireleri için yeni ve yenilikçi bir kanser takip yöntemidir. COVID-19 salgınının ardından, teletıp hizmetleri onkolojide giderek artan bir gereksinim haline gelmiş ve hasta navigasyon hizmetlerininde dahil olduğu teletıp uygulamalarının bu alanda kullanımı artmıştır. Ancak bu konu üzerine çalışmalar literatürde halen sınırlıdır. Bu çalışma, hemşire liderliğindeki telenavigasyon programının kolorektal kanserli (KRK) hastalarda semptom yönetimi ve psikososyal uyum üzerindeki etkisini değerlendirmeyi amaçlamaktadır.

Yöntem: Bu randomize kontrollü çalışmada, İstanbul'daki bir kanser merkezine başvuran 60 kolorektal kanser hastası rastgele atama yöntemi kullanılarak navigasyon uygulanan ve navigasyon uygulanmayan olmak üzere iki gruba ayrıldı. Hemşire Liderliğindeki Telenavigasyon Programı (HLTP) kapsamında WhatsApp uygulaması aracılığıyla 3 seans görüşme yapıldı. Araştırma kapsamında semptom yönetimi ve psikososyal uyum ölçümleri değerlendirildi. Bulgular, istatistiksel yöntemler kullanılarak analiz edildi.

Bulgular Hemşire liderliğindeki telenavigasyon programının KRK'li hastalar üzerindeki etkisini araştıran çalışmada, müdahale (navigasyon uygulanan) ve kontrol (navigasyon uygulanmayan) gruplarının her ikisinde de N-SAS ölçeğinin fiziksel ve psikolojik iyilik hâli alt ölçekleri ile toplam puanlarında anlamlı düşüşler gözlemlendi ($p<.05$). Ancak gruplar arasında N-SAS alt ölçekleri ve toplam puanları açısından anlamlı bir fark bulunmadı ($p>.05$). Öte yandan navigasyon uygulanan grupta zamanla PAIS-SR toplam puanlarında anlamlı bir azalma görülürken ($p<.05$), navigasyon uygulanmayan grupta anlamlı bir değişiklik saptanmadı ($p>.05$). Bu bulgular, HLTP'nin KRK hastalarında psiko-sosyal uyumu anlamlı düzeyde artırdığını ($p<.05$), ancak fiziksel semptomların yönetimindeki etkilerinin yetersiz olduğunu göstermektedir ($p>.05$).

Sonuç: Hemşire liderliğinde telenavigasyon programlarının kanser hastalarına göre uyarlanmış engellilik odaklı müdahaleler olduğu gerçeği göz önünde bulundurulduğunda, mevcut çalışma kolorektal kanser hastalarının psikososyal refahını iyileştirmeyi amaçlayan onkoloji hemşireleri için değerli bir rehberlik sağlamaktadır. Bu çalışmanın sonucunda, hemşire liderliğindeki telenavigasyon programının daha çeşitli popülasyonları ve daha büyük örneklem gruplarını içeren ek çalışmalar yoluyla değerlendirilmesi önerilmektedir.

Anahtar Kelimeler: Kolorektal kanser, Hasta navigasyonu, Teletıp

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***Corresponding author/Sorumlu yazar:** Health Sciences University, Hamidiye Faculty of Nursing, Department of Oncology Nursing, İstanbul, Türkiye
[1*]Email: zynpdlgr96@gmail.com, [2]Email: elif.donmez@sbu.edu.tr

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INTRODUCTION

Colorectal cancer (CRC) affects approximately 1.9 million individuals annually, making it the third most prevalent cancer and the second leading cause of cancer-related mortality worldwide [1,2]. The CRC diagnosis imposes a substantial physiological and psychological burden, often disrupting social aspects of life, including interpersonal relationships and responsibilities. Psychosocial adjustment in cancer patients reflects their ability to adapt to these disease-related changes, where inadequate symptom management or poor psychosocial adjustment can negatively influence disease progression and treatment response [3-6]. CRC patients, particularly those with advanced disease, frequently experience symptoms such as pain, fatigue, nausea, vomiting, constipation, diarrhea, weight loss, rectal bleeding, anorexia, and delirium [7]. Alongside physical symptoms, they often endure psychosocial challenges, including adjustment issues, depression, anxiety, reduced quality of life, and diminished self-confidence [5,8]. Interventions aimed at symptom management and psychosocial adjustment include individual and group-based education, psychoeducation, therapeutic support, and navigation programs, provided either face-to-face or via telehealth technologies [9-13].

The COVID-19 pandemic accelerated telehealth adoption for oncology patients, leading to increased research in this field. Telehealth applications developed for oncology aim to improve access to care, service outcomes, and continuity while minimizing hospital visits [14-16]. Telemedicine in oncology has demonstrated benefits for timely diagnosis, cost reduction, patient comfort, and improved access to treatment [17,18].

Oncology navigation, first developed in the USA in the early 1990s [19,20], aims to reduce barriers to cancer care, especially for socioeconomically disadvantaged groups. Navigation services help remove financial, emotional, scheduling, communication, and healthcare access obstacles, ensuring timely cancer screening, diagnosis, treatment, and post-treatment follow-up [21-23]. Recently, navigation has expanded into telehealth, giving rise to telenavigation, which provides patient and family education led by trained navigators. Telenavigation enhances care quality, supports therapeutic communication, assists in end-of-life care, addresses financial issues, and reduces healthcare access barriers. Oncology nurse navigators, using telecommunication, offer continuous patient support, improving healthcare access, patient satisfaction, and care quality [16-18,24]. While telenavigation is known to support physical and psychological symptom management and patient satisfaction, its full impact remains under-researched [13,25-28]. Telehealth remains uncommon in Turkish oncology care and often depends on individual efforts. Further studies are necessary to explore telehealth's applicability across all levels of oncology care in developing countries like Turkiye.

In this context, the present study aims to assess the impact of a nurse-led telenavigation (NTP) program on symptom management and psychosocial adjustment in CRC patients.

METHOD

Study Design and Participants

This research was conducted from July 2021 to February 2022 at a hospital in Istanbul, using a pretest-posttest control group design within the outpatient chemotherapy unit of the medical oncology clinic. The chemotherapy unit is equipped with four fully automated robotic chemotherapy preparation units, 85 chemotherapy administration chairs, and a patient education room. Before their first chemotherapy session, all patients receive a 15-minute education session from an educational nurse, covering side effect management, dietary recommendations and emergency hospitalization guidelines. Each patient also receives an information booklet summarising the content of the session.

The study population comprised an annual average of 608 outpatients with CRC attending the clinic. A power analysis using G*Power 3.1 determined that a sample size of 28 participants per group (56 total) would provide 80% power with a 5% margin of error and an effect size of 0.767 (df=54; t=2.004). Accounting for a 10% attrition rate, a target of 62 participants was set. During the study, 118 CRC patients were screened; 34 were excluded for not meeting inclusion criteria. Ultimately, 62 patients who met eligibility criteria and consented were enrolled, with 30 assigned to the experimental (navigated) group and 30 to the control group. One participant from each group was excluded due to non-responsiveness during follow-up, resulting in a final sample size of 60 participants Participants were randomly assigned based on registration order at the chemotherapy unit. The study adhered to the CONSORT (Consolidated Standards of Reporting Trials) guidelines [29], with a CONSORT flowchart provided in Figure 1. Eligibility criteria for participants included the following:

- Aged 18 years or older
- Diagnosed with CRC
- Independent WhatsApp use (or assisted by a relative)
- No cognitive impairments
- Undergoing chemotherapy at the outpatient chemotherapy unit.

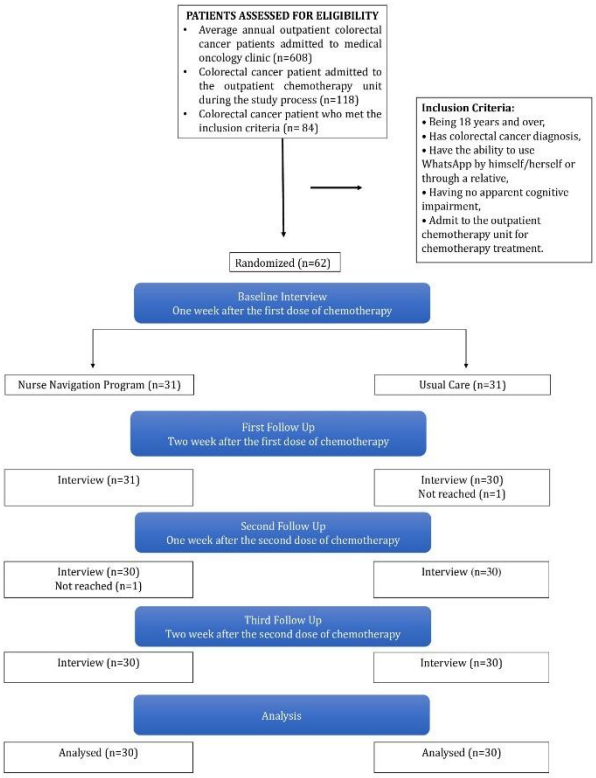

Figure 1. CONSORT flowchart

Intervention

Nurse-led Telenavigation Program (NTP)

The NTP consisted of tailored interventions, including colorectal cancer education, psycho-oncological support, and a nurse-managed telephone helpline. Personalized CRC education and psycho-oncological counseling were delivered through WhatsApp video calls, with sessions lasting 45-60 minutes each, while the nurse-led telephone support was conducted via voice calls. Intervention components of the NTP are illustrated in Figure 2.

Outcome Measures

Data were collected using three tools: the Descriptive Characteristics Information Form, the Nightingale Symptom Assessment Scale (N-SAS), and the Psychosocial Adjustment to Illness-Self-Report Scale

(PAIS-SR). Data collection was conducted via Google Forms to minimize patients' risk of COVID-19 exposure.

Descriptive Characteristics Information Form: This form, structured based on relevant literature [23,27,30,31], was divided into three sections to capture socio-demographic characteristics and CRC diagnosis details.

Nightingale Symptom Assessment Scale (N-SAS): Developed in Turkish by Can and Aydiner in 2009, the N-SAS assesses cancer-related symptom intensity, providing a reliable measure of physical, social, and psychological well-being (Cronbach's alpha = .93). Scores on the 38-item scale reflect overall quality of life and well-being, with lower scores indicating fewer disease or treatment-related issues [32]. The N-SAS showed a reliability score of .834 in this study.

Psychosocial Adjustment To Illness Scale-Self Report (PAIS-SR): Originally created in English by Derogatis in 1986, the PAIS-SR evaluates psychosocial adaptation to physical illness, scored across seven subcategories with a total of 46 items. Scores below 35 indicate good psychosocial adjustment, scores between 35 and 51 reflect moderate adjustment, and scores above 51 indicate poor adjustment. The PAIS-SR demonstrated a reliability score of .881 in this study [33].

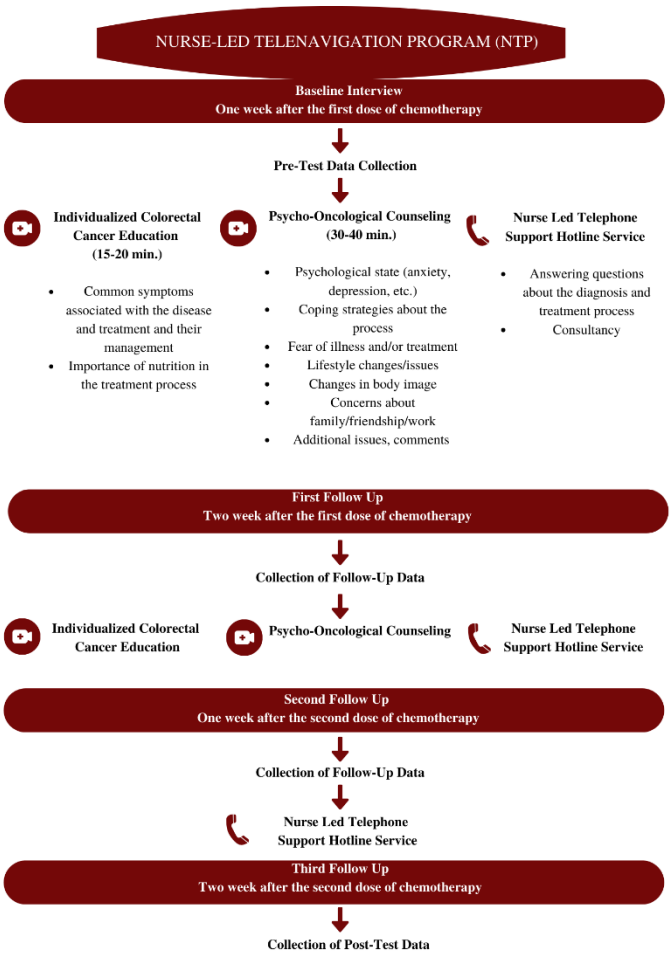

Figure 2. Nurse-led telenavigation program

Ethical Approval

This study was approved by the University of Health Sciences Hamidiye Clinical Research Ethics Committee (date: 04.05.2021, approval number: 32378), in accordance with the Declaration of Helsinki. Informed consent was obtained from all participants. Further study details are available at ClinicalTrials.gov (identifier: NCT05571098).

Statistical Analysis

Data analysis was performed using IBM SPSS version 22. Descriptive measures (count, percentage, mean, and standard deviation) were calculated. Normality was assessed through kurtosis and skewness values. The chi-square and Fisher's exact tests were used to analyze categorical differences between groups, while independent t-tests compared continuous data between groups. Repeated measures ANOVA and the Bonferroni test were applied for within-group changes. A p-value of <0.05 was considered statistically significant.

RESULTS

The study included 60 participants, with 30 in the nurse-navigated group and 30 in the non-navigated group. The average age of participants was 60.13 years (SD=10), and the majority were male (78.33%), married (86.7%), had either elementary or secondary education (73.3%), perceived their income level as good (68.3%), and were not actively employed (90%). Most participants were diagnosed with non-metastatic cancer (58.3%), had undergone surgery (73.3%), and had not received radiotherapy (81.7%) (Table 1).

Table 1. Baseline demographic and health-related characteristics of participants by study group (n=60)

Variables	Nurse Navigated	Non-Navigated	Total	Statistics
Age, Mean±SD	62.27±9.08	58 ±10.56	60.13±10	p=0.099
Sex (%)				
Female	23.3	20	21.7	p=0.754
Male	76.7	80	78.3	
Marital status (%)				
Married	86.7	86.7	86.7	p=0.647
Single/ Widowed/ Divorced	13.3	13.3	13.3	
Education (%)				
Elementary and secondary school	76.7	70	73.3	p=0.559
High school and university	23.3	30	26.7	
Income (%)				
Poor	30	33.3	31.7	p=0.781
Good	70	66.7	68.3	
Employment status (%)				
Employed	6.7	13.3	10	p=0.389
Unemployed	93.3	86.7	90	
Diagnosis (%)				
Metastatic	50	33.3	41.7	p=0.19
Non-Metastatic	50	66.7	58.3	
Surgical treatment (%)				
Yes	70	76.7	73.3	p=0.386
No	30	23.3	26.7	
Radiotherapy (%)				
Yes	20	16.7	18.3	p=0.5
No	80	83.3	81.7	

p<.05 was considered significant

Both the navigated and non-navigated groups showed significant reductions in physical and psychological well-being sub-dimensions and total scale scores (p<.05) at baseline and after the first, second, and third follow-ups. However, there were no significant differences between the groups in N-SAS sub-dimensions and total scores (p>.05) (Table 2).

Table 2. Nightingale Symptom Assessment Scale measure baseline score and after NTP (n=60)

Nightingale Symptom Assessment Scale		Nurse Navigated	Non-Navigated	Statistics
Psychological Well-Being (Mean±SD)	Baseline	0.936±0.585	0.713±0.675	p[a]=0.177
	First follow up	0.583±0.458	0.440±0.451	p[a]= 0.227
	Second follow up	0.947±0.589	0.790±0.640	p[a]=0.328
	Third follow up	0.573±0.446	0.533±0.505	p[a]=0.746
	F/p[b]	21.713/0.000	11.227/0.000	
	Bonferroni	1>2,4	1>2; 3>2,4	
Physical Well-Being (Mean±SD)	Baseline	0.767±0.368	0.713±0.431	p[a]=0.608
	First follow up	0.227±0.237	0.203±0.198	p[a]=0.681
	Second follow up	0.732±0.346	0.763±0.359	p[a]=0.729
	Third follow up	0.275±0.243	0.300±0.323	p[a]=0.736
	F/p[b]	83.685/0.000	37.803/0.000	
	Bonferroni	1,3>2,4	1,3>2,4	
Social Well-Being (Mean±SD)	Baseline	0.158±0.188	0.129±0.184	p[a]=0.547
	First follow up	0.121±0.159	0.113±0.195	p[a]=0.857
	Second follow up	0.213±0.239	0.221±0.287	p[a]=0.903
	Third follow up	0.167±0.206	0.179±0.291	p[a]=0.848
	F/p[b]	3.893/0.032	2.539/0.110	
	Bonferroni	3>2	-	
Total Score (Mean±SD)	Baseline	0.620±0.329	0.519±0.357	p[a]=0.256
	First follow up	0.310±0.251	0.25±0.212	p[a]=0.335
	Second follow up	0.630±0.332	0.591±0.331	p[a]=0.651
	Third follow up	0.338±0.255	0.338±0.290	p[a]=0.991
	F/p[b]	54.637/**0.000**	23.111/**0.000**	
	Bonferroni	1,3>2,4	1>2; 3>2,4	

a:Independent Groups t-test; b:Repeated Measures Anova Test; Baseline:One week after the first dose of chemotherapy; First follow up:Two week after the first dose of chemotherapy; Second follow up:One week after the second dose of chemotherapy; Third follow up:Two week after the second dose of chemotherapy

Psychosocial adjustment levels were measured with PAIS-SR in both groups. In the non-navigated group, no significant differences were observed in healthcare orientation, vocational environment, or total scores at the first, second, or third follow-ups compared to baseline. However, the navigated group showed a significant reduction (p<.05) (Table 3).

Significant differences were noted between the groups in healthcare orientation, sexual relationships, and extended family relationships (p<.05). Specifically, the navigated group had decreased healthcare orientation scores by the second follow-up and decreased scores in both healthcare orientation and extended family relationships by the third follow-up compared to the non-navigated group. Conversely, sexual relationship scores were lower in the non-navigated group than in the navigated group during the first follow-up. Overall, PAIS-SR total scores in the navigated group showed significant reductions over time (p<.05), while the non-navigated group showed no significant change (Table 3).

Table 3. Psychosocial Adjustment to Illness Scale-Self Report measure baseline score and after NTP (n=60)

Psychosocial Adjustment to Illness Scale		Nurse Navigated	Non-Navigated	P
Healthcare Orientation	Baseline	3.200±2.905	3.967±3.557	0.364
	First follow up	2.467±2.649	3.900±3.566	0.082
	Second follow up	2.133±2.113	4.100±3.294	**0.008**
	Third follow up	2.067±2.149	4.133±3.298	**0.006**
	F/p	12.515/**0.000**	0.693 /0.444	
	Bonferroni	**1>2,3,4**		
Vocational Environment	Baseline	6.200±3.326	6.267±2.828	0.934
	First follow up	5.933±3.473	6.367±2.810	0.597
	Second follow up	5.633±3.327	6.667±2.644	0.188
	Third follow up	5.633±3.316	6.633±2.593	0.198
	F/p	5.924 /**0.007**	1.327 /0.264	
	Bonferroni	**1>3**		
Domestic Environment	Baseline	2.033±2.173	2.067±1.982	0.951
	First follow up	2.000±2.150	2.067±1.982	0.901
	Second follow up	1.867±1.995	2.200±1.864	0.506
	Third follow up	1.867±1.995	2.200±1.864	0.506
	F/p	1.663/0.208	1.000 /0.326	
Sexual Relationships	Baseline	0.620±0.329	0.519±0.357	p[a]=0.256
	First follow up	0.310±0.251	0.25±0.212	p[a]=0.335
	Second follow up	0.630±0.332	0.591±0.331	p[a]=0.651
	Third follow up	0.338±0.255	0.338±0.290	p[a]=0.991
	F/p	54.637/**0.000**	23.111/**0.000**	
Extended Family Relationships	Baseline	0.667±0.922	0.900±1.296	0.425
	First follow up	0.433±0.728	0.867±1.279	0.114
	Second follow up	0.467±0.730	0.967±1.245	0.063
	Third follow up	0.400±0.621	1.067±1.285	**0.014**
	F/p	3.418/0.058	2.071 /0.147	

Social Environment	Baseline	4.833±3.668	4.267±4.177	0.579
	First follow up	4.600±3.276	4.167±3.975	0.647
	Second follow up	4.667±3.122	4.700±4.061	0.972
	Third follow up	4.633±3.000	4.800±4.106	0.858
	F/p	0.415 /0.665	1.868 /0.182	
Psychological Distress	Baseline	2.633±2.312	2.067±2.420	0.358
	First follow up	2.100±2.234	1.933±2.545	0.788
	Second follow up	2.467±2.270	2.533±2.649	0.917
	Third follow up	2.133±2.097	2.300±2.521	0.782
	F/p	3.67/0.065	2.853 /0.070	
PAIS-SR Total	Baseline	25.333±12.680	22.900±14.399	0.490
	First follow up	23.267±12.709	22.433±14.268	0.812
	Second follow up	23.067±12.140	24.700±14.303	0.635
	Third follow up	22.300±12.524	24.433±14.080	0.538
	F/p	5.277/**0.014**	2.259 /0.139	
	Bonferroni	**1>2,3,4**		

Baseline:One week after the first dose of chemotherapy; First follow up:Two week after the first dose of chemotherapy; Second follow up: One week after the second dose of chemotherapy; Third follow up:Two week after the second dose of chemotherapy

DISCUSSION

This study aimed to evaluate the impact of the Nurse-led Telenavigation Program on symptom management and psychosocial adjustment in patients with colorectal cancer. The findings revealed that while the program had significant effects on psychosocial adjustment, it did not have a statistically significant impact on symptom management. The Nurse-led Telenavigation Program in this study included individualized colorectal cancer education, psycho-oncological counseling, and a nurse-led telephone support hotline, all delivered via the WhatsApp application. Following the intervention, reductions in the physical and psychological well-being sub-dimensions, as well as total scale scores, were observed in both the navigated and non-navigated groups. However, no significant differences were found between the two groups.

This result may be expected, as patients' symptom burden is typically high in the first weeks after chemotherapy, and symptom management often improves in the subsequent weeks. It is likely that patients can manage the common symptoms of colorectal cancer without the need for nurse navigation, which may explain the lack of significant difference between the experimental and control groups.

A review of studies on improving symptom management shows both supportive and differing results. For example, a study by Mooney et al. (2014) asked patients to report the occurrence and severity of symptoms developed during chemotherapy to oncology physicians and nurses via a computer-based telephone monitoring system. The researchers found no significant change in symptom severity between the control and experimental groups [34]. Similarly, in a study by Traeger et al., the impact of a nurse-led symptom management intervention for patients with non-metastatic cancer (including colorectal, breast, and lung cancers) undergoing chemotherapy was evaluated. The study found no significant differences between the groups in any of the symptoms (p>.05) [35].

However, contrasting results were reported in a study by Mooney et al., which developed a tele-reporting system for monitoring and managing symptoms during chemotherapy. Patients were asked to report their symptoms daily, and if the symptoms exceeded pre-determined thresholds, they received intervention via a nurse-managed support line. This study found a significant decrease in the occurrence and intensity of symptoms (excluding diarrhea) in the experimental group after the intervention compared to the control group (p<.05) [27]. Additionally, a study by Lai et al. assessed a nurse-led care program for patients with breast cancer undergoing chemotherapy. The program significantly reduced the occurrence of oral mucositis, fatigue, peripheral neuropathy, and distress in the intervention group compared to the control group [26].

The results of the current study also indicated that the navigated group exhibited lower psychosocial adjustment levels compared to the non-navigated group following the intervention. Many studies have shown that telehealth interventions positively influence psychosocial adjustment. For instance, Loiselle et al. examined the effect of an eight-week computer-based multimedia information intervention on the psychosocial adjustment of individuals newly diagnosed with breast or prostate cancer. The study found that the intervention group showed a more significant increase in cancer knowledge and maintained a higher level of functional quality of life, with improved satisfaction in supportive care (p<.05). However, the intervention did not demonstrate an impact on self-esteem, self-management, or optimistic thinking (p>.05) [36].

Lichiello et al. studied young adult cancer survivors and assessed the impact of a psychosocial telehealth intervention. The post-intervention results showed greater acceptance of their condition, psychological relief, and reductions in anxiety and feelings of hopelessness (p<.05) [37]. A systematic review of telephone interventions for symptom management in adult cancer patients found that these interventions reduced depression, anxiety, and emotional distress [12]. Furthermore, a meta-analysis investigating the effects of telehealth interventions on breast cancer patients' quality of life and psychological well-being found improvements in both quality of life and self-efficacy, with reductions in depression and perceived stress (p<.05). However, no significant difference was found between groups regarding anxiety levels (p>.05) [38].

Nurse counseling plays a crucial role in the psychosocial adjustment of cancer patients, particularly in advising them about potential challenges post-treatment. Nurse navigators are essential at this stage, and counseling provided through tele-navigation programs is expected to improve psychosocial adjustment in patients.

Limitations

While the study yielded significant findings, several limitations should be considered when interpreting the results. First, the research was conducted at a single center, which limits the generalizability of the findings to a broader population of cancer patients. Additionally, the sample group discussed in the study may not represent all colorectal cancer patients, potentially affecting the applicability of the results. Furthermore, since the Nurse-led Telenavigation Program (NTP) was delivered using telehealth methods, the findings may not be applicable to individuals who are unfamiliar with or do not have access to telehealth services.

CONCLUSION

This study employed the Nurse-led Telenavigation Program (NTP) to explore the experiences of colorectal cancer patients, yielding important insights into symptom management and psychosocial adjustment. The results indicate that the NTP was effective in enhancing patients' psychosocial adjustment, though it did not significantly improve symptom management. Given that nurse navigation programs are disability-focused interventions tailored to cancer patients, this study provides valuable guidance for oncology

nurses aiming to improve the psychosocial well-being of colorectal cancer patients.

To strengthen future research in this field, it is recommended that NTP be evaluated with larger, more diverse sample groups that include a variety of cancer types. Expanding the program's content and scope, while ensuring its continuity through digital tools (such as applications), would further enhance its effectiveness. Including caregivers in the program is essential for providing holistic care, and integrating NTP into routine patient care by oncology nurses in outpatient chemotherapy units could increase its accessibility across different treatment settings.

Ethical Approval: *2021/32378 Hamidiye Clinical Research Ethics Committee of Health Sciences University*

Conflict of Interest: *The authors have no conflicts of interest to declare.*

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GRIP STRENGTH AND GRIP ENDURANCE IN HEALTHY YOUNG ADULTS: RELATIONSHIP WITH UPPER EXTREMITY FUNCTIONAL CAPACITY AND ACTIVITIES OF DAILY LIVING

SAĞLIKLI GENÇ ERİŞKİNLERDE KAVRAMA KUVVETİ VE KAVRAMA ENDURANSI: ÜST EKSTREMİTE FONKSİYONEL KAPASİTESİ VE GÜNLÜK YAŞAM AKTİVİTELERİ İLE İLİŞKİSİ

Melissa Köprülüoğlu Koç[1*], Elvan Felekoğlu[1], İlknur Naz Gürşan[1]

[1]Department of Physiotherapy and Rehabilitation, Faculty of Health Sciences, İzmir Katip Çelebi University, İzmir, Türkiye

ABSTRACT

Objective: Several sensorimotor parameters are necessary for optimal upper extremities function. Grip strength (GS) and grip endurance (GE) may be among these main parameters. Our study investigated the association of GS and dynamic GE with upper extremity functional capacity and activities of daily living in healthy young adults.

Method: Forty-five healthy participants aged 19-23 years were included in our study. All of the participants had no trauma, surgery or diagnosis related their upper extremities. A hand dynamometer was used for GS and dynamic GE measurements. Upper extremity functional capacity with Unsupported Upper Extremity Test (UULEX) and activities of daily living (ADL) with the Glittre ADL test were evaluated. The Spearman Correlation Analysis used to investigate relationship between variables.

Results: It was found that the GS values of participants correlated to UULEX (on the dominant side; r=0.409 and on the non-dominant side; r=0.385, p<0.05) and Glittre ADL test durations (on the dominant side; r=-0.515 and on the non-dominant side; r=-0.457, p<0.05). However, there was no significant relationship between dynamic GE and protocols with UULEX and Glittre ADL durations (p>0.05).

Conclusion: According to our results, upper extremity functional capacity and ADL were related to GS but not dynamic GE. In clinical practice, evaluating GS can provide an idea for upper extremity functional capacity and ADL.

Key Words: Grip strength, Grip endurance, Upper extremity function, Functional capacity, Activities of daily living

ÖZ

Amaç: Optimal üst ekstremite fonksiyonu için birçok sensorimotor parametreler gereklidir. Kavrama kuvveti (KK) ve kavrama enduransı (KE) bu temel parametreler arasında olabilir. Çalışmamız sağlıklı genç erişkinlerde KK ve dinamik KE'nin üst ekstremite fonksiyonel kapasitesi ve günlük yaşam aktiviteleri ile ilişkisini incelemektedir.

Yöntem: Çalışmamıza 19-23 yaş aralığında 45 sağlıklı katılımcı dahil edildi. Katılımcıların hiçbiri üst ekstremiteleri ile ilişkili travma, cerrahi ya da tanıya sahip değildi. KK ve dinamik KE için el dinamometresi kullanıldı. Üst ekstremite fonksiyonları Desteksiz Üst Ekstremite Testi (DÜET) ve günlük yaşam aktiviteleri Glittre Günlük Yaşam Aktiviteleri Testi ile değerlendirildi. Değişkenler arasındaki ilişkinin incelenmesi için Spearman Korelasyon Analizi kullanıldı.

Bulgular: Katılımcıların KK değerleri, hem DÜET (dominant tarafta; r=0.409 ve non-dominant tarafta; r=0.385, p<0.05) hem de Glittre testi süreleri (dominant tarafta; r=-0.515 ve non-dominant tarafta; r=-0.457, p<0.05) ile ilişkili bulundu. Ancak dinamik KE'nin DÜET ve Glittre test süreleri ile anlamlı bir ilişkisi yoktu (p>0.05).

Sonuç: Sonuçlarımıza göre üst ekstremite fonksiyonel kapasitesi ve günlük yaşam aktiviteleri KK ile ilişkili iken dinamik KE ile ilişkili değildir. Klinik pratikte KK'yi değerlendirmek, üst ekstremite fonksiyonel kapasitesi ve günlük yaşam aktiviteleri hakkında fikir verebilir.

Anahtar Kelimeler: Kavrama kuvveti, Kavrama enduransı, Üst ekstremite fonksiyonu, Fonksiyonel kapasite, Günlük yaşam aktiviteleri

INTRODUCTION

There are certain requirements for the upper extremity to perform daily function. Wide range of motion, synchronized movement of many joints, muscle strength, power, endurance, and some sensorimotor parameters form the basis of this requirement [1,2]. The grip strength (GS) has been widely researched and showed as a predictor of functional performance and an essential parameter in the upper extremities assessment [3,4].

The GS reflects the maximum effort derived from upper extremity muscles. However, an individual is more likely to use a maintained gripping than maximum gripping in activities of daily living (ADL) [5]. It indicates the necessity of grip endurance (GE) for daily life. The dynamic part of ADL requires repeated gripping, and the static part requires the ability to maintain submaximal GS [6]. For this reason, the GE includes two separate components such as dynamic and static. This

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***Corresponding author/Sorumlu yazar:** İzmir Katip Çelebi University, Faculty of Health Sciences, Department of Physiotherapy and Rehabilitation, İzmir, Türkiye
[1*]Email: kopruluoglumelissa@gmail.com, [2]Email: elvanfelekoglu@gmail.com, [3]Email: ilknurnaz4@gmail.com

information shows that several sensorimotor parameters including GS and GE are necessary for optimal function of upper extremities [1]. Although these parameters is necessary for ADL, there is no comprehensive study evaluated the place of GS and GE in upper extremity function and which is the most important parameter for ADL.

Limited studies are exploring GE and related functional parameters in healthy individuals [7-9]. A study examining the concurrent validity of the GE tests found that the test is related to the six-minute walking distance, a standardized exercise capacity test [8]. Another study on healthy older women without chronic disease emphasized the relationship between GE and postural stability [9]. In a study that investigated the correlation of GE between maximum GS and the hand functional score in patients with rheumatoid arthritis and in healthy controls, the relationship of GE was not observed in healthy controls [8].

There is a hypothesis that the evaluation of dynamic GE may provide a predictor of function and functional capacity compared to the assessment of static GE [10]. However, to the best of our knowledge, no study examined the relationship of dynamic GE with upper extremity functional capacity and ADL. Our study aimed to clarify whether there is a relationship between GS and GE with upper extremity functional capacity and ADL.

METHOD

Study Design and Participants

Our study was planned as a cross-sectional study. Our sample size was calculated by GPower 3.1.9.7. program as 42 participants with a 0.50 effect size, a 5% type1 error, and 95% power. The participants aged 18-25 years were included in the study. The reason why the participants were in this age range is that the literature reports that muscle strength decreases as of the third decade of life and the anabolic process becomes more dominant in the muscle structure affecting function [11]. We included undergraduate students in İzmir Katip Çelebi University Faculty of Health Sciences as participants. The exclusion criteria were identified as a history of upper extremity trauma and surgery, diagnosis with a neurological, rheumatological, orthopeadic, or any chronic disease, and no cooperation for assessment [12].

Outcome Measures

Before the test sessions, the sociodemographic data of the participants were recorded in a form. This form included personal data such as age, height, weight, smoking status, history of surgery and/or trauma, pharmacological or medical history. For the assessment of dynamic GE, it was used 6-repetitive and 12-repetitive protocols. Upper extremity exercise capacity with Unsupported Upper Extremity Test (UULEX) and ADL with The Glittre Activities of Daily Living Test (ADL) was evaluated. For all assessment protocols, we followed a specific order, and the assessments were carried out in the order of "UULEX-Glittre ADL-GS-GE". A half-hour resting interval between the first two tests and a 15-minute resting interval between the other tests was given.

Grip Strength and Endurance Protocols: The maximal grip strength was measured by a hand dynamometer (Lafayette Professional Hand Dynamometer 5030L1, USA). The test procedure was carried out in compliance with the American Society of Hand Therapists' recommendations [13]. The measurement was received on both sides with a 1-min break and three consecutive grips were performed with a 15-sec break [14,15]. Participants placed in the standard test position were asked to squeeze the dynamometer with a maximum force three times and maintain the force for 3 sec with no verbal feedback. The average values were recorded as maximal grip strength [13].

Dynamic GE was evaluated by 6-repetitive and 12-repetitive tests. Because of the lack of a standardized method of measuring GE, we used two different dynamic GE protocols for examining the relationship between upper extremity functional capacity and ADL. Participants were placed in the same standardized test position as the grip strength assessment. They have performed 6 and 12 maximal grips controlled by a metronome (1-sec contraction/1-sec rest). It was recorded that calculated change of the first 3 grip values and the last 3 grip values [15].

Unsupported Upper Extremity Test (UULEX): The UULEX test was performed by Takahashi et al. is a performance-based test that evaluates the functional capacity of the upper extremities [16]. This parameter reflects aerobic capacity of upper extremity that is necessary to maintain function/activity. To perform the test, participants were seated in a chair in front of the test system, which consists of eight horizontal levels (120 cm height × 84 cm width) 5 cm apart and 8 cm wide. The bottom level was placed so that it was at the participant's knee alignment. Five different bars (0.2 kg, 0.5 kg, 1 kg, 1.5 kg, and 2 kg) were used during the test. During the test, the participants moved the bar held at shoulder width to the corresponding levels and returned to their hip joint accompanied by a metronome (thirty movements per minute). The starting and ending point for all movements is the hip joint of participants. The first level was maintained for 2 mins and the other levels for 1 min and the test was started with a 0.2 kg bar. When the participants reached the highest level, the bar was replaced with a 0.5 kg bar, and the test was continued at the maximum level. The bar weight was increased by 0.5 kg per minute and advanced to a weight of 2 kg. The participants continued the test until they experienced anything that would limit their ability to continue the test at the maximum level. The total score was recorded as test duration. Additionally, before and after the test, heart rate (HR), peripheral oxygen saturation (SpO_2), arm fatigue, and dyspnea evaluated using the modified Borg scale were recorded.

The Glittre Activities of Daily Living Test (Glittre ADL): The Glittre ADL test as described by Skumlien et al. involves a 10 m circuit where the participants perform a sequence of activities in the shortest time [17]. During the test, all participants carried a backpack containing 2.5 kg for women and 5.0 kg for men. The test started in a seated position. At the starting signal, they stood up from this position and then walked for 5 m, climbed up and down the two-step stairs (17 cm high and 27 cm deep for each step), and walked for another 5 m. When they reached two shelves adjusted shoulder and waist level for participants at the end of the 10 m, three objects with 1 kg each that were placed on the top shelf were moved singly to the bottom shelf, down to the ground, back to the bottom shelf, and to the top shelf again. After this activity, they turned back and walked the same track and this circuit was performed five laps as quickly as possible. The main performance parameter was the total time that the completion of the test. Before and after the test, HR, SpO_2, dyspnea, and fatigue were recorded.

Ethical Approval

We received approval from the İzmir Katip Çelebi University, Department of Physiotherapy and Rehabilitation, Education, Research and Innovation Laboratories to carry out our researcb (İzmir Katip Çelebi University Non-interventional Research Ethics Board, Date: 20.01.2022, Approval number: 0609). During the study, we followed the principles of the Declaration of Helsinki. After we explained briefly the purpose and assessments of the study to participants, the informed consent form was given, and they were asked to sign that.

Statistical Analysis

All of the analyses were performed by IBM SPSS Statistics (Version 20.0. Armonk, NY: IBM Corp.). The normal distribution was checked by the Shapiro-wilk test. The variables were presented as mean/standard deviation or median/ first and third quartile or percentage (%). Paired sample t test was used to compare pre- and post- hemodynamic responses for UULEX and Glitttre ADL test. Bivariate correlations between the GS and two dynamic GE protocols,

and UULEX and the Glittre ADL test were examined using Spearman correlation coefficient. Correlations were interpreted as “strong” (r>0.70), “moderate” (r=0.50–0.69), “weak” (r=0.26–0.49), and “very weak or no correlation” (r=0.00–0.25) [18]. The p values <0.05 were considered to indicate statistical significance.

RESULTS

Forty-five individuals participated in the study. Most of the participants were female gender (71.11%) and never smoker (60.0%). The mean age of participants was 21.48 with a minimum 19 and maximum 23 years. Participants sociodemographic variables such as weight, height, and body mass index were presented in Table 1. Only four participants (8.89%) used the left hand dominantly.

Table 1. Sociodemographic variables of participants

Variables	Statistics
Gender (men/women)	13/32
Age (years)	21.48±1.12
Height (cm)	169.37±9.24
Weight (kg)	65.56±15.22
Body mass index (kg/m^2)	22.88 ±2.31
Smoking status n (%)	
Never	27 (60.00)
Ex-smoker	2 (4.44)
Active smoker	16 (35.56)

cm:centimetre; kg:kilogram; kg/m2:kilogram/square meter; n:number; %:percentage; data presented as mean ±standart deviation or median (1./3. quartiles) according to the normal distribution

In Table 2, participants’ grip functional variables, Glittre ADL test, and UULEX test results were presented. The UULEX test durations of the participants range from 384.6 to 549.8 and median 454.7 sec. After the UULEX test, a mean of 12 beats in HR, a mean of 0.15 units in SpO_2, a mean of 0.2 units in dyspnea, and a mean of 1.5 units in general fatigue were observed according to the resting state (Table 2).

Table 2. Test results of participants

Variables		Statistics
Grip strength (kg)	Dominant	31.0 (27.5/44.3)
	Non-dominant	29.2 (25.0/42.0)
6-rep dynamic grip endurance % (change)	Dominant	8.4 (3.2/12.3)
	Non-dominant	9.2 (6.3/16.7)
12-rep dynamic grip endurance % (change)	Dominant	17.5 (12.4/22.8)
	Non-dominant	21.7 (13.9/28.4)
UULEX test duration (sec)		454.7 (384.6/549.8)
Unsupported Upper Extremity Test	**Pre-test**	**Post-test**
Heart rate (beats/min*)	82.43 ±14.21	94.02 ±16.30
SpO_2	98.30 ±2.71	98.15 ±1.49
Dyspnea (0-10)	0.54 ±0.94	0.74 ±0.95
General Fatigue (0-10)*	1.76 ±1.34	3.26 ±1.79
Arm Fatigue (0-10)*	0.72 ±1.01	5.05 ±1.91
Glittre Activities of Daily Living test duration (sec)	127 (113/141)	
Glittre Activities of Daily Living Test	**Pre-test**	**Post-test**
Heart rate (beats/min)*	79.42 ±13.22	119.89 ±22.85
SpO_2*	98.02 ±1.48	97.27 ±1.74
Dyspnea (0-10)*	0.43 ±0.69	2.40 ±1.53
General Fatigue (0-10)*	1.43 ±1.24	2.97 ±1.26

*kg:kilogram; %:percentage; sec:second; beats/min:beats/minutes; SpO2:peripheric oxygen saturation; data presented as mean ±standart deviation or median (1./3. quartiles) according to the normal distribution. *There is a statistically significant difference between pre-and post-values according to paired sample t-test results.*

The Glittre ADL test durations, HR, SpO2, dispnea, and general fatigue were presented. The test durations of the participants range 86 to 213 sec and median 127 sec. After the Glittre ADL test, a mean of 40 beats in HR, a mean of 0.75 units in SpO2, approximate 2 units in dyspnea, a mean of 1.5 units in general fatigue, and a mean of 4 units in arm fatigue were observed according to the resting state (Table 2). While heart rate and fatigue values increased significantly in both tests after the test, pre- and post-values of SpO2 and dyspnea increased only in the Glittre test. All participants completed the Glittre ADL test however 26.67% (n=12) of the participants left the test due to arm fatigue and 6.67% (n=3) due to inability to adapt to the metronome.

The relationship between grip functional variables with upper extremity functional capacity and ADL was shown in Table 3. There was no significant correlation between dynamic GE in both protocols with UULEX and Glittre ADL test results (p>0.05). However, the GS related to UULEX (r=0.409 and 0.385, dominant and non-dominant sides respectively, Figure 1) and Glittre ADL test results (r=-0.515 and -0.457, dominant and non-dominant sides respectively, Figure 2).

Table 3. Correlation of grip functional variables with upper extremity functional capacity and activities of daily living

Correlation	Unsupported Upper Extremity Test Duration			Glittre Activities of Daily Living Test Duration		
	P	R	95% CI	P	r	95% CI
DGS	0.005	0.409	-0.662/-0.170	0.004	-0.515	0.185/0.714
NDGS	0.008	0.385	-0.621/0.119	0.011	-0.457	0.224/0.613
D6RGE	0.401	0.071	-0.329/0.595	0.692	0.086	-0.306/0.293
ND6RGE	0.526	0.109	-0.141/0.535	0.451	0.174	-0.413/0.142
D12RGE	0.509	0.120	-0.383/0.463	0.498	0.128	-0.416/0.187
ND12RGE	0.611	0.242	-0.099/0.512	0.483	0.152	-0.448/0.108

*DGS:Dominant Grip Strength; NDGS: Non-dominant Grip Strength; D6RGE:Dominant Grip Endurance-6 repetitions; ND6RGE:Non-dominant Grip Endurance-6 repetitions; D12RGE:Dominant Grip Endurance-12 repetition; ND12RGE:Non-dominant Grip Endurance-12 repetitions; *Spearman correlation analysis was performed to examine the relationship between variables.*

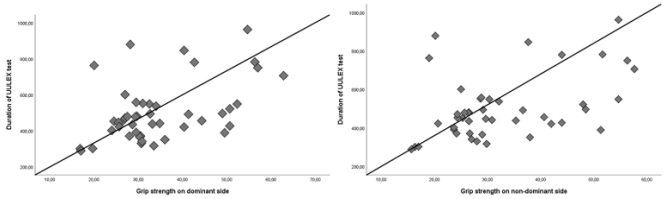

Figure 1. Correlations between UULEX and GS

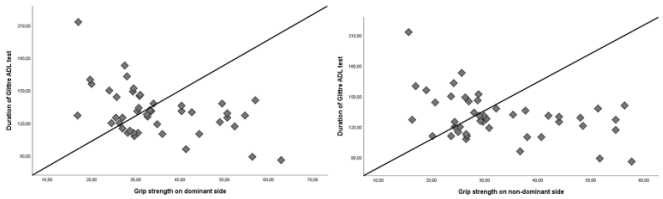

Figure 2. Correlations between Glittre ADL and GS

DISCUSSION

In this study, we examined the relationship between GS and dynamic GE (6-rep and 12-rep protocols) with upper extremity functional capacity and ADL. The main findings of this study were that both UULEX and Glittre ADL tests showed a weak to moderate correlation with GS in healthy young adults. Our study is the first study to examine the relationship between dynamic GE with upper extremity functional capacity and ADL.

The GS and GE are the important part of the assessment of upper extremity muscular function [19]. The studies revealed that GS decreases during the lifespan depending on the decrease in sensation of the hand, loss of hand dexterity, fibers of muscle impairment, and

degeneration of the nervous system, and this loss may hinder activities in daily life such as bathing, dressing, and eating and contribute to the loss of independence [20,21]. Dynamic GE is an essential part of several daily activities such as writing, screwing, cleaning a floor or window, and gardening [15]. The assessment of both GE and dynamic GE may form a clearer frame for overall functional capacity in healthy individuals [22]. In our study, the GS was associated with UULEX test duration weakly but dynamic GE was not related to UULEX test. Although the studies in the literature revealed that the upper extremity functional capacity requires strength, manual dexterity, and motor coordination, there are no studies supporting that GE is associated with upper extremity exercise capacity [11]. Our study supports the evidence that strength is associated with upper extremity functional exercise capacity and reveals that GS is weakly related. This weak correlation may be due to the activation of larger muscle groups in functional exercise capacity evaluations including overhead movement patterns compared to GS measurements. However, no relationship was observed with GE, which we expected to be associated with upper extremity functional exercise capacity. The reason for this may be the dominant different energy system. Although the UULEX test requires repeated movement in a long duration (approximately 8-12 min and max 15 min) [11], the assessment of dynamic GE includes movement with 6 and 12 repeats in 12 and 24 sec. While the dominant system for UULEX is an aerobic system, an anaerobic system is the dominant energy system for both of the dynamic GE measurements.

Dependence on ADLs of individuals is related to the risk of morbidity and mortality [23]. Thus, assessment of the ADL is an important part of planning rehabilitation. The optimization of activities in daily life requires a sufficient active range of motion [24], optimal muscle parameters including mass, strength, and physical performance [25], good motor coordination including balance, dexterity, etc. parameters, good perceptual and cognitive skills [26]. The authors said that for ADL performance, a combination of self-report scales and performance-based assessment may be the best way to shed light on the impairment of the individuals [27]. However, there is a need for assessment tools that are simple, time- and cost-effective, and predictive of ADL performance for healthy individuals. Our study hypothesized that GS and GE assessments may be a predictor of ADL in healthy young. As a result of our study, it emphasized that ADL and GS were related but it is not associated with GE. Our findings are in line with previous studies that a decrease in GS is associated with problems in performing activities and that GS is important for the maintenance of ADL [28]. Although it was mentioned GE is a part of the ADL [5], it was observed no relationship between both protocols of the dynamic GE results with the duration of the Glittre ADL test in our study. The reason for this result may have originated from the dynamic GE test protocols that require maximal gripping in short intervals (1 sec contraction-1 sec rest). Gripping performed in the ADL may be longer intervals, less repetitive, and require submaximal strength. Besides, according to our knowledge, there is no evidence about the relationship dynamic GE and ADL in the literature. Therefore, these results are the first evidence of GE and ADL. Future studies may use different dynamic GE protocols and examine its relationship with ADL.

In our study, the GS of the participants had approximately similar values those previously reported in studies that investigated maximal GS values in the Turkish healthy young population [29,30]. The number of studies examining dynamic GE is limited in healthy young adults. Kopruluoglu et al. found that healthy controls had a percentage change rate of 16.16% on the dominant side and 16.37% on the non-dominant side in the 10-rep dynamic GE test [6]. Women aged 70.5 ±3.6 years had a percentage change rate of 30.27% on the dominant side and 35.68% on the non-dominant side in 12-rep dynamic GE performed with contractions for 3 secs and 5-sec rest in Konstantina's study [22]. Our participants had lower percentage change rates in both dynamic GE test protocols compared to the other test results. The reason for these results may have originated from younger participants in our study. On the other hand, no study was found in healthy young adults for the UULEX and Glittre ADL test. However, the UULEX and Glittre test durations of our participants were slightly higher than the durations of our participants and it means that our participants had better ADL performance and lower upper extremity functional capacity [11,31]. Additionally, it was observed a significant increase in hemodynamic responses after testing for both tests and both tests caused significant fatigue. It indicates that both tests provide loading in our participants. At the same time, more than 25% of the participants terminated the UULEX test due to arm fatigue. As the test involves repetitive arm flexion until exhaustion, termination of the test due to fatigue symptoms is an expected situation for the healthy population, as seen in previous studies [32].

Limitations

There are some limitations of our study. We aimed to include only healthy young adults aged 18-25 years and the women is dominant in gender distribution. This limits the generalizability of our results. Besides this study may be expanded with a larger group by deepening and more detailed method that will consider different variable such as gender, body composition etc. Additionally, we ignored the confounding variables in the analysis of the relationship between GS and GE with upper extremity functional capacity and ADL. The variables such as gender, physical activity level, and muscle mass in the upper extremity may be confounding factors related to our parameters. Further studies considering these limitations are needed to support and be clearer about these results. There is a significant knowledge gap in the literature in understanding the basic parameters required for the upper extremity to maintain normal function. Although the parameters required for normal function are known, detailed studies are needed to discuss the place of GS and GE among these parameters. Besides, these dynamic GE protocols are not appropriate to examine the relationship between upper extremity functional capacity and ADL. In future studies, this relationship may be examined with different dynamic GE protocols. We used all of the study performance-based tests. In future studies that are planned to evaluate these parameters, especially in groups with upper extremity functional problems, evaluations based on participant statements as well as performance-based evaluations can be performed.

CONCLUSION

In conclusion, we found that upper extremity functional capacity and ADL correlated to GS. Along with the findings about GE is not associated with upper extremity functional capacity and ADL, these results open space for assessment of GS in healthy young adults may be predictive of upper extremity functional capacity and ADL. In clinical practice, evaluations focus on upper extremity strength. However, our findings, which emphasize that strength is related to ADL and functional capacity in the upper extremity, highlighted importance of these parameters for the upper extremity. In particular, upper extremity functional capacity is often ignored and we included this important variable in our study. The results of GS tests can serve as a potential preliminary screening analysis for upper extremity functional capacity and ADL in healthy young adults. We also conducted the study in a healthy population. The results of this population may shed light on future studies conducted different population and disease. This is one of the areas where there is still a lack of research. For discussing and generalizing our study results, the literature needs more studies in wider age ranges and different patient groups.

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EXAMINING THE RELATIONSHIP BETWEEN PEDIATRIC NURSES' ATTITUDES TOWARDS ETHICAL PRINCIPLES AND MORAL INTELLIGENCE LEVELS

PEDİATRİ HEMŞİRELERİNİN ETİK İLKELERE YÖNELİK TUTUMLARI İLE AHLAKİ ZEKÂ DÜZEYLERİ ARASINDAKİ İLİŞKİNİN İNCELENMESİ

Zeynep Erkut[1*], Zeynep Aközlü[2], Selmin Köse[3]

[1]School of Nursing, Maltepe University, İstanbul, Türkiye

[2]Department of Medical Services and Techniques, Vocational School, Maltepe University, İstanbul, Türkiye

[3]Department of Nursing, Faculty of Health Sciences, Biruni University, İstanbul, Türkiye

ABSTRACT

Objective: This study aimed to examine the relationship between the moral intelligence levels of nurses working in pediatric clinics and their perspectives on ethical principles.

Method: This study was cross-sectional and descriptive-correlational. The data for the study were provided by nurses working in pediatric clinics of two public and two private hospitals in Istanbul between October and December 2022. There were 140 pediatric nurses in the study's sample. The Yakut-Moral Intelligence Scale, the Ethical Principles Attitude Scale, and the Descriptive Characteristics Form were used as data collection tools.

Results: The overall Ethical Principles Attitude Scale score ranged from 35 to 175 with a mean of 142.26±18.18. The average Moral Intelligence score fell between 20 and 100, with a mean of 78.53±10.15. It was found that there was a positive but low correlation between the total mean scores of the Yakut-Moral Intelligence Scale and the Ethical Principles Attitude Scale ($p<0.001$). It was determined that the moral intelligence levels of nurses working in private hospitals, nurses participating in a scientific event on ethics, and nurses who were satisfied with their professional life were higher ($p<0.05$).

Conclusion: It was found that nurses working in pediatric clinics, where providing care in line with ethical principles is very important, have high attitudes towards ethical principles. In this study, the finding of a positive relationship between pediatric nurses' attitudes towards ethical principles and their moral intelligence levels was considered as an important contribution to the scientific literature.

Key Words: Attitude, Ethics, Moral intelligence, Pediatric nursing

ÖZ

Amaç: Bu çalışmanın amacı, pediatri kliniklerinde çalışan hemşirelerin ahlaki zekâ düzeyleri ile etik ilkelere ilişkin bakış açıları arasındaki ilişkiyi incelemek olarak belirlendi.

Yöntem: Bu çalışma kesitsel ve tanımlayıcı-ilişkiseldir. Araştırmanın verileri, 2022 yılının Ekim ve Aralık ayları arasında, İstanbul'daki iki kamu ve iki özel hastanenin pediatri kliniklerinde çalışan hemşireler tarafından sağlandı. Çalışmanın örneklemi 140 pediatri hemşiresinden oluştu. Veri toplama aracı olarak Yakut-Ahlaki Zeka Ölçeği, Etik İlkeler Tutum Ölçeği ve Tanımlayıcı Özellikler Formu kullanıldı.

Bulgular: Etik İlkeler Tutum Ölçeği toplam puanı ortalaması 142.26±18.18 olup, 35 ile 175 arasında değişmektedir. Ahlaki Zeka toplam puanı ortalaması 78.53±10.15 olup, 20 ile 100 arasında değişmektedir. Yakut-Ahlaki Zeka Ölçeği ile Etik İlkeler Tutum Ölçeği toplam puan ortalamaları arasında pozitif yönde ancak düşük derecede korelasyon ilişkisi olduğu bulundu ($p<0.001$). Özel hastanede görev yapan hemşirelerin, etik konusunda bilimsel bir etkinliğe katılan hemşirelerin ve meslek hayatından memnun olan hemşirelerin ahlaki zeka düzeylerinin daha yüksek olduğu belirlendi ($p<0.05$).

Sonuç: Etik ilkeler doğrultusunda bakım vermenin oldukça önemli olduğu pediatri kliniklerinde görevli hemşirelerin etik ilkelere ilişkin tutumlarının yüksek olduğu bulundu. Bu araştırmada pediatri hemşirelerinin etik ilkelere ilişkin tutumları ile ahlaki zeka düzeyleri arasında pozitif bir ilişkinin olduğunun bulunması bilimsel literatüre önemli bir katkı olarak değerlendirildi.

Anahtar Kelimeler: Tutum, Etik, Ahlaki zeka, Pediatri hemşireliği

INTRODUCTION

Nursing is a profession in which adherence to ethical principles is fundamental during the delivery of care to patients [1]. Values, beliefs, and ethical action patterns in clinical decision-making shape nursing practices that do not depend only on technical skills and knowledge [2]. Pediatric nurses are in direct and constant contact with children and their parents, and ethical decision-making is integral to their daily work [3]. Since children have limited autonomy, nurses in pediatric settings have a direct and unavoidable responsibility to protect the rights of the children they serve [4]. The high ethical sensitivity of pediatric nurses contributes to professionalization and directly affects the quality of nursing care given to patients [5].

Moral intelligence includes the skills to distinguish right from wrong, be honest, make appropriate choices for the patient's benefit, and provide the best care in line with ethical principles [6]. The qualities that serve as the foundation for cultivating these abilities are respect, self-control, empathy, conscience, tolerance, compassion, and justice [7]. Individuals with high moral intelligence consistently link their

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***Corresponding author/Sorumlu yazar:** School of Nursing, Maltepe University, İstanbul, Türkiye

[1*]Email: erkutzeynep@hotmail.com, [2]Email: zakozlu@gmail.com, [3]Email: selminkose@yahoo.com

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behaviors to moral and ethical standards and maintain a balance between their views and values [8]. Moral intelligence guides human behavior and helps individuals take intelligent and optimal actions [9]. The literature states that nurses' ethical performance is greatly affected by their moral intelligence and criteria [10]. Thus, this study aimed to examine the relationship between pediatric nurses' attitudes toward ethical principles and their moral intelligence levels. Within the scope of the research, answers to the following questions were sought:

- What are pediatric nurses' moral intelligence scores?
- What views do pediatric nurses have regarding morality?
- Do the sociodemographic traits of pediatric nurses and their moral intelligence levels correlate with one another?
- Do the sociodemographic traits of pediatric nurses and their views on ethical principles correlate with one another?
- Do pediatric nurses' opinions toward ethical principles and their moral intelligence levels correlate with one another?

METHOD

Study Design

Nurses employed in the pediatric departments of four hospitals (two public hospitals, and two private hospitals) in Istanbul provided the data for this descriptive and cross-sectional study between October 1, 2022, and December 1, 2022.

Participants

The study population consisted of 208 pediatric nurses (public hospital:166, private hospitals:42). The sample formula of the known population was used to determine the number of participants included in the study. The sample size was accepted as p (probability of the event under study) =0.5 in the 95% confidence interval, and it was determined as 136 pediatric nurses for ±5% sampling errors. One hundred forty pediatric nurses participated in the study. 67.3% of the population has been reached. The random sampling method, one of the non-probability methods, was used to select the sample.

Inclusion Criteria:

- Being a nurse working in the pediatric setting,
- Volunteering to participate in the research,

Exclusion Criteria:

- Filling in the scales incompletely.

Outcome Measures

Descriptive Characteristics Form: This form, which was prepared by the researchers to determine the participants' sociodemographic characteristics, consists of a total of 14 questions [5,8,10].

Ethical Principles Attitude Scale (EPAS): This scale is used to determine nurses' attitudes towards ethical principles in health care practices. It is a valid and reliable (Cronbach's Alpha=0.85) scale developed by Uysal Kasap and Bahçecik in 2020. The scale includes 35 items and six sub-dimensions (Justice, Non-maleficence, Veracity, Respect for Autonomy, Beneficence, Confidentiality-Keeping Secret). The reliability coefficient of the "Justice" sub-dimension of the scale was calculated as .77, the "Non-maleficence" sub-dimension as .65, the "Veracity" sub-dimension as .63, the "Respect for Autonomy" sub-dimension as .65, the "Beneficence" sub-dimension as .72, and the "Confidentiality-Keeping Secret" sub-dimension as .65. Strongly agree (5), agree (4), neutral (3), disagree (2), and strongly disagree (1) are the possible scores for the 5-point Likert-type items that make up the EPAS. On the scale, there are four reversal items. The scale yields scores that range from 35 to 175. Nurses who score around 175 on the scale are considered to have a strong attitude toward ethical principles, whilst those who score near 35 are considered to have a low approach [11]. The scale's Cronbach's Alpha rating in the current investigation was 0.934.

Yakut-Moral Intelligence Scale (Y-MIS): This scale is used to measure the level of moral intelligence of individuals. It is a valid and reliable (Cronbach's Alpha=0.845) scale developed by Yakut and Yakut in 2021. The scale includes 20 questions and four sub-dimensions (Empathy, Conscience, Self-control, and Courtesy). The reliability coefficient of the "Empathy" sub-dimension of the scale was calculated as .827, the "Conscience" sub-dimension as .791, the "Self-control" sub-dimension as .803, and the "Courtesy" sub-dimension as .772. Five-point Likert-type questions make up the scale's items (1 being strongly disagree, 2 disagree, 3 neutral, 4 agree, and 5 strongly agree). On the scale, 20 represents the lowest score and 100 represents the greatest. A high moral intelligence level is shown by the high score. All age groups and educational levels beyond primary school can use the scale [12]. The scale's Cronbach's Alpha value in the current investigation was determined to be 0.917.

Data Collection

Data were collected from the participants using the "Descriptive Characteristics Form", "Yakut-Moral Intelligence Scale" and "Ethical Principles Attitude Scale". The data were obtained through Google Forms (Google LLC, Menlo Park, CA, USA). Answering the questions took an average of 20 minutes.

Ethical Approval

Before the research, necessary permissions were obtained from the Maltepe University Non-Interventional Studies Ethics Committee (date: 01.09.2022, approval number: 2022/21-08) and the hospitals where the study would be conducted. Before the study, an informed consent form was presented to the participants. After the participants approved the form, they were included in the study. It was made clear to participants that they could leave the study at any moment.

Statistical Analysis

Software called IBM SPSS (Statistical Package for the Social Science) 22.0 was used to examine the study's results. Categorical variables were given as number and percentage; continuous variables were given as mean and standard deviation. Using the Kolmogorov-Smirnov test, the data's normal distribution was examined. It was found that the data were not normally distributed. Mann-Whitney U test was used to compare the mean ranks of two independent groups and Kruskal-Wallis H analysis was used to compare the mean ranks of more than two independent groups. Spearman's correlation analysis was used to determine the relationship between the scale scores. Croanbach's alpha value was found using reliability analysis. At significance levels of $p<0.05$, the data were assessed at a 95% confidence range.

RESULTS

The participants' ages ranged between 20 and 56 years, with a mean of 28.6±6.258 years. It was revealed that 86.4% of the nurses were women, and 60% were undergraduate graduates. Further, 69.3% of the participants worked in the public hospital, 37.1% in the neonatal intensive care unit, and 85.7% in day and night shifts. 47.1% and 49.3% of the participants worked for 1 to 5 years. 43.6% of the participants stated that they were partially satisfied with their professional life, 70.7% faced an ethical problem, and 42.1% of them stated that they participated in a congress, symposium, or training on ethics (Table 1).

It was determined that the participants got an average score of 142.26±18.18 from the EPAS, 35.18±5.49 from the justice sub-dimension, 17.01±2.73 from the non-maleficence sub-dimension, 19.00±2.45 from the veracity sub-dimension, 32.26±5.43 from the respect for autonomy sub-dimension, 21.71±3.49 from the beneficence sub-dimension, and 17.07±2.66 from the confidentiality-keeping secret sub-dimension. Further, the participants got 78.53±10.15 points from the Y-MIS, 19.00±2.93 points from the empathy sub-dimension,

21.02±3.26 points from the conscience sub-dimension, 18.28±3.32 points from the self-control sub-dimension, and 20.72±3.20 points from the courtesy sub-dimension of this scale (Table 2).

Table 1. Descriptive characteristics of participants (n=140)

Variables		N	%
Gender	Female	121	86.4
	Male	19	13.6
Marital status	Married	50	35.7
	Single	90	64.3
Having kids	Yes	36	25.7
	No	104	74.3
Educational status	Less than a bachelor's degree	22	15.7
	Bachelor's degree	84	60
	Postgraduate degree	34	24.3
Employed institution	Public hospital	97	69.3
	Private hospital	43	30.7
Worked unit	Pediatric emergency	25	17.9
	Pediatric surgery	14	10
	Pediatric unit	35	25
	Pediatric intensive care unit	14	10
	Neonatal intensive care unit	52	37.1
Types of work shifts	Day shift only	20	14.3
	Day and night shift	120	85.7
Working period in the nursing profession	Less than 1 year	14	10
	Between 1 and 5 years	66	47.1
	Between 6 and 10 years	33	23.6
	11 years and above	27	19.3
Working period in pediatric settings	Less than 1 year	30	21.4
	Between 1 and 5 years	69	49.3
	Between 6 and 10 years	26	18.6
	11 years and above	15	10.7
Satisfaction with professional life	Yes	58	41.4
	Partially	61	43.6
	No	21	15
Encountering an ethical problem	Yes	99	70.7
	No	41	29.3
Participation in a congress, symposium, or training on ethics	Yes	59	42.1
	No	81	57.9

Min:minimum; Max:maximum; SD:standard deviation

Table 2. Distribution of the mean scores of the scales and subscales (n=140)

Scales	Min	Max	X̄±SD
EPAS	52	166	142.26±18.18
Justice	8	40	35.18±5.49
Non-maleficence	4	20	17.01±2.73
Veracity	11	26	19.00±2.45
Respect for autonomy	8	40	32.26±5.43
Beneficence	6	25	21.71±3.49
Confidentiality, secret-keeping	8	20	17.07±2.66
Y-MIS	30	100	78.53±10.15
Empathy	8	25	19.00±2.93
Conscience	9	25	21.02±3.26
Self-control	7	25	18.28±3.32
Courtesy	7	25	20.72±3.20

EPAS:Ethical Principles Attitude Scale; Y-MIS:Yakut-Moral Intelligence Scale; Min:minimum; Maxmaximum, SD:standard deviation

A low degree of positive correlation was found between the Y-MIS total mean score and the EPAS total mean, and a statistically significant relationship was found (r=0.335, p<0.001) (Table 3).

In the comparison of the scores of the participants from the Y-MIS in terms of the institution they work for, it was found that those who work in private hospitals, those who are satisfied with their professional life, and those who attend a congress, symposium or training on ethics had higher average scores from the Y-MIS. There was a statistically significant difference between them (p<0.05) (Table 4).

Table 3. The relationship between the EPAS and Y-MIS (n=140)

Scales	N	R	p
EPAS	140	0.335*	**0.000****
Y-MIS			

EPAS:Ethical Principles Attitude Scale; Y-MIS:Yakut-Moral Intelligence Scale

Table 4. Comparison of EPAS and Y-MIS total mean scores according to some variables of participants (n=140)

Variables	EPAS		Y-MIS	
	X̄±SD	Test p	X̄±SD	Test p
Gender				
Female	143.31±17.25	940.50[a] 0.203	78.65±10.09	1133[a] 0.920
Male	135.57±22.65		77.78±10.75	
Having kids				
Yes	139.16±25.47	1.856[a] 0.939	76.41±13.87	1854[a] 0.933
No	143.33±14.86		79.26±8.45	
Educational status				
Less than a bachelor's degree	142.72±23.91	0.720[b] 0.698	79.77±14.92	2.378[b] 0.305
Bachelor's degree	141.94±17.30		78.16±7.83	
Postgraduate degree	142.76±16.55		78.64±11.69	
Working period in the nursing profession				
Less than 1 year	143.42±16.72	4.479[b] 0.214	80.42±8.96	1.106[b] 0.776
Between 1 and 5 years	139.54±17.86		78.62±9.88	
Between 6 and 10 years	145.18±15.31		77.81±6.45	
11 years and above	144.74±22.44		78.22±10.15	
Employed institution				
Public hospital	140.75±17.93	1.670[a] 0.061	77.48±9.30	1549[a] **0.015***
Private hospital	145.67±18.46		80.90±11.62	
Satisfaction with professional life				
Yes	141.91±21.15	0.866[b] 0.649	80.58±11.78	12.057[b] **0.002***
Partially	142.83±16.95		77.67±9.36	
No	141.57±12.58		75.38±5.69	
Encountering an ethical problem				
Yes	142.55±16.44	1986[a] 0.840	79.20±9.34	1919[a] 0.614
No	141.56±22.02		76.92±11.85	
Participation in a congress, symposium, or training on ethics				
Yes	142.33±19.92	2297[a] 0.696	79.30±12.06	1912[a] **0.044***
No	142.20±16.92		77.97±8.53	

*EPAS:Ethical Principles Attitude Scale; Y-MIS:Yakut-Moral Intelligence Scale; SD:Standard deviation; [a]Mann-Whitney U test; [b]Kruskal-Wallis H test,*p<0.05*

DISCUSSION

Nursing, which focuses on people, is a profession in which moral values and adherence to ethical principles are essential [1]. The attitudes of pediatric nurses who care for susceptible children towards ethical principles are critical [13]. Issues such as more violations of rights in pediatric settings, children being more vulnerable than adults, establishing relationships with the family, and participation of parents in child-related decisions increase the importance of ethical principles in pediatric nursing. In addition, compliance with ethical principles in pediatric nursing becomes more complicated with technological developments, care models, and cultural care practices [3,14,15]. The pediatric nurses' attitude in the current study towards ethical principles was considered quite positive in terms of professionalization. Because the high attitudes of pediatric nurses toward ethical principles will directly affect the quality of nursing care, they give to patients. Similar to this study, in a study conducted with nurses working in pediatric oncology clinics, it was found that nurses' adherence to ethical codes was optimal [16]. In a study examining the knowledge and practices of pediatric nurses on ethical codes, most pediatric clinic nurses act in compliance with ethical codes [17].

Generally speaking, intelligence is the capacity to think, learn, and adjust to new circumstances. There are various forms of intelligence, such as moral, emotional, spiritual, and cognitive [18]. Moral intelligence is the ability to distinguish between right and wrong [19]. In other words, it refers to an individual's ability to process and manage ethical problems [20]. Moral intelligence is not inherited; it is a skill that is acquired and developed [21]. It was discovered that the moral intelligence scores of the nurses participating in the present study were relatively high (78.53±10.15; within a range of 20-100). In a study conducted in Iran, it was found that the moral intelligence score of the nurses was 4.35±0.56 (min:1-max:5) [1]. In another study conducted with 99 nurses working in the emergency department, similar to our study, nurses' moral intelligence levels were found to be high [6]. Two studies conducted in Iran at different times reported that nurses' moral intelligence scores were reasonable, similar to our study [10,22]. In a study conducted with nurses working in departments other than pediatric settings (internal units, surgical units, intensive care units, and polyclinic) in Türkiye, it was found that the moral intelligence levels of the participants were high [21]. In a study conducted with nurses working in the intensive care unit, unlike our study, it was determined that the moral intelligence of most nurses (n=168; 62.9%) was moderate [8]. The high moral intelligence level of the nurses included in our study, and the nurses participating in other studies may confirm the nursing profession's moral and professional nature [1,6,10,21,22].

The relationship between nurses' moral intelligence and their attitudes toward ethical principles has not been the subject of any research in the literature. Our findings were described in this context using a small number of indirect sources, and our comments on those findings were kept front and center. This study found that nurses' views toward ethical principles and their moral intelligence levels had a weakly positive correlation. Nurses who score well on moral intelligence also exhibit a strong commitment to ethical standards. Following ethical guidelines when providing patient care is essential for nurses in this professional field. Human intellect is directly tied to comprehending and putting ethical concepts into practice [20]. Strong ethical beliefs and adherence to them [19] are necessary for moral intelligence, which is the cornerstone and foundation of nursing ethics [23]. Based on the results of this study, it can be concluded that raising nurses' moral intelligence levels is crucial to boosting their adherence to ethical standards. Furthermore, the significance nurses have on moral principles and the moral actions they exhibit in their caregiving practices is evidenced by their high moral intelligence scores. Nurses with high moral intelligence levels provide better treatment and are more satisfied with their patients. According to a study conducted in Turkey, nurses' care behaviors improve in tandem with their moral intelligence levels [21]. Additionally, an Iranian study found a strong and direct correlation between moral intelligence and nursing care quality [22]. According to a different study, patient satisfaction and nurses' moral intelligence level were significantly and favorably correlated [10].

The current study ascertained that the moral intelligence levels of the nurses who were satisfied with their professional life and participated in a congress, symposium, or training on ethics were higher. Other characteristics (such as gender, having children, and education level) of the nurses participating in our study did not affect their moral intelligence scores. In contrast to our findings, a study that sought to ascertain the moral intelligence levels of nurses found a direct and substantial correlation between the moral intelligence levels of nurses and the number of years they had worked [1]. A study involving emergency department nurses revealed that female nurses possessed higher levels of moral intelligence. Furthermore, the work experience of nurses did not influence their moral intelligence in this study, which is consistent with our studies [6]. In another study, it was discovered that none of the demographic variables of nurses had a critical effect on moral intelligence [22]. This difference in the results of the research may be due to factors such as the individual characteristics of the participants, the geographical region they live in, the working environment, and organizational, social, and cultural characteristics.

Limitations

This study was limited to the participation of pediatric nurses working in the pediatric units of four hospitals in Istanbul. As a result, the results of this study might not be applicable to pediatric nurses employed in other hospitals, areas, or nations.

CONCLUSION

The study's findings highlighted the importance of pediatric nurses' moral intelligence development in delivering ethical patient care. By drastically altering nurses' perspectives on patients, themselves, and the profession, determining and developing moral intelligence abilities can aid in professional growth. Therefore, one of the prerequisites for this profession in the modern world has been the ability of nurses to develop moral intelligence and gain moral knowledge. Determining and enhancing the moral intelligence of nurses employed in pediatric and other clinics is crucial in this regard. To enhance nurses' moral and ethical thought processes, ongoing in-service training should be conducted. In future studies, training programs should be developed to improve the moral intelligence levels of nurses, and the reflections of such training programs on nursing care practices should be examined.

In conclusion, our study offers valuable and meaningful insights for both nursing education and clinical practices. The findings highlight the critical role of in-service training, ethical awareness initiatives, and moral intelligence development programs in enhancing the quality of care in pediatric nursing. Such educational programs are expected to improve not only individual nursing practices but also team interactions and overall healthcare standards. Moreover, fostering ethical principles and moral intelligence can enable nurses to build stronger trust-based relationships with patients and their families while effectively adhering to professional nursing ethics. In this context, our study emphasizes the necessity of developing long-term strategies aimed at enhancing nurses' ethical sensitivity and integrating these strategies into clinical settings.

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THE EFFECT OF HEALTH BELIEF MODEL BASED WEB EDUCATION ON DIABETIC FOOT CARE KNOWLEDGE, BEHAVIOURS AND SELF-EFFICACY IN INDIVIDUALS WITH TYPE 2 DIABETES

SAĞLIK İNANÇ MODELİ TEMELLİ WEB EĞİTİMİNİN TİP 2 DİYABETLİ BİREYLERDE DİYABETİK AYAK BAKIMI BİLGİSİ, DAVRANIŞLARI VE ÖZ-YETERLİLİK ÜZERİNDEKİ ETKİSİ

Yakup Sarpdağı[1*], Cantürk Çapık[2]

[1]Department of Nursing, Faculty of Health Sciences, Van Yüzüncü Yıl University, Van, Türkiye

[2]Department of Public Health Nursing, Faculty of Nursing, Ataturk University, Türkiye

ABSTRACT

Objective: The aim of this study was to evaluate the effect of web training based on the Health Belief Model on knowledge, behavior and self-efficacy in diabetic foot care in individuals with type 2 diabetes who are at low risk of diabetic foot problems.

Method: The study, conducted as a randomized controlled trial at a Family Health Center between December 2021 and May 2023, included 142 individuals with type 2 diabetes (71 in the experimental group and 71 in the control group), as determined by power analysis. The experimental group received web-based training in six modules, one every two weeks, based on the Health Belief Model, followed by a 3-month follow-up.

Results: The descriptive characteristics (gender, age, education, etc.) and disease-related variables (presence of other chronic diseases, diabetes treatment type, etc.) of both experimental and control groups were found to be homogeneous ($p>0.05$). In the analyses conducted according to the hypotheses, post-intervention diabetic foot knowledge scores ($t=7.582$; $p=0.001$), foot care behavior scores ($t=3.125$; $p=0.002$), and self-efficacy scores ($t=4.337$; $p=0.001$) showed statistically significant increases in the experimental group compared to the control group. In within-group comparisons, significant differences were observed between pre-test and post-test scores in the experimental group regarding knowledge level ($t=-7.382$; $p=0.001$), behaviors ($t=-2.100$; $p=0.039$), and self-efficacy ($t=-3.198$; $p=0.002$), while no significant changes were detected in the control group ($p>0.05$).

Conclusion: This study shows that web education based on the Health Belief Model is effective in increasing foot care knowledge, behaviours and self-efficacy of individuals with low-risk type 2 diabetes. Nurses can improve care behaviours and manage patient care more effectively by providing accessible trainings to their patients through digital education methods. Digital trainings provide an important contribution to the literature by demonstrating that it can be an effective tool in nursing practice and its potential to improve patients' care behaviours.

Key Words: Diabetes mellitus, Diabetic foot, Health belief model, Self efficacy, Web based

ÖZ

Amaç: Bu çalışmanın amacı, diyabetik ayak sorunu yaşama olasılığı düşük olan tip 2 diyabetli bireylerde Sağlık İnanç Modeli'ne dayalı web eğitiminin diyabetik ayak bakımı konusundaki bilgi, davranış ve öz yeterlilik üzerindeki etkisini değerlendirmektir.

Yöntem: Aralık 2021-Mayıs 2023 tarihleri arasında bir Aile Sağlığı Merkezi'nde randomize kontrollü çalışma olarak yürütülen bu araştırmaya, güç analizi sonucunda belirlenen 142 tip 2 diyabet hastası (deney grubu: 71, kontrol grubu: 71) dahil edildi. Deney grubu sağlık İnanç Modeline dayalı olarak iki haftada bir olmak üzere altı modül halinde web tabanlı eğitim aldı ve ardından 3 aylık bir takip gerçekleştirildi.

Bulgular: Deney ve kontrol gruplarının tanımlayıcı özellikleri (cinsiyet, yaş, eğitim vb.) ile hastalıkla ilişkili değişkenlerinin (diğer kronik hastalık varlığı, diyabet tedavi şekli vb.) homojen olduğu belirlendi ($p>0.05$). Hipotezler doğrultusunda yapılan analizlerde, deney grubunda eğitim sonrası diyabetik ayak bilgisi puanlarının ($t=7.582$; $p=0.001$), ayak bakımı davranış puanlarının ($t=3.125$; $p=0.002$) ve öz-yeterlilik puanlarının ($t=4.337$; $p=0.001$) kontrol grubuna göre anlamlı derecede arttığı görüldü. Grup içi karşılaştırmalarda deney grubunda bilgi düzeyi ($t=-7.382$; $p=0.001$), davranışlar ($t=-2.100$; $p=0.039$) ve öz-yeterlilik ($t=-3.198$; $p=0.002$) açısından pre-test ve post-test puanları arasında anlamlı farklar bulunurken kontrol grubunda bu değişim anlamlı değildi ($p>0.05$).

Sonuç: Bu çalışma, Sağlık İnanç Modeli'ne dayalı web eğitiminin, düşük riskli tip 2 diyabetli bireylerin ayak bakımı bilgisi, davranışları ve öz-yeterliliklerini artırmada etkili olduğunu göstermektedir. Hemşireler, dijital eğitim yöntemleriyle hastalarına erişilebilir eğitimler sunarak bakım davranışlarını iyileştirebilir ve hasta bakımını daha etkili yönetebilirler. Dijital eğitimler, hemşirelik pratiğinde etkili bir araç olabileceğini ve hastaların bakım davranışlarını iyileştirme potansiyelini ortaya koyarak literatüre önemli bir katkı sağlamaktadır.

Anahtar Kelimeler: Diyabetik ayak, Diabetes mellitus, Sağlık inanç modeli, Öz yeterlilik, Web temelli

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***Corresponding author/Sorumlu yazar:** Van Yüzüncü Yıl University, Faculty of Health Sciences, Department of Nursing, Van, Türkiye

[1*]Email: yakup_sys@hotmail.com, [2]Email: c_capik36@hotmail.com

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INTRODUCTION

Diabetes mellitus (DM) has emerged as one of the most significant health challenges of the 21st century due to its increasing prevalence, morbidity, and mortality risks [1]. Globally, approximately half a billion people live with diabetes, with nearly 80% of the diabetes burden borne by low- and middle-income countries, including Turkey [2]. According to the International Diabetes Federation (IDF) report, there are over 9 million diabetic patients aged 20-79 in Turkey, with an adult prevalence rate of 15.9% [3]. Diabetes is a disease that reduces the quality of life, increases the duration of hospitalisation and leads to serious complications. One of these complications is diabetic foot [4]. Which leads to reduced quality of life, frequent and prolonged hospitalizations, high costs, limb loss, and death [5]. The lifetime risk of developing diabetic foot complications for individuals with diabetes ranges between 19-34% [6], with an average prevalence of 6.4% [7]. Globally, a diabetes-related lower-limb amputation occurs every 30 seconds [8], and the 5-year mortality rate following diabetes-related amputations is estimated to be 70%, exceeding that of many common cancers such as breast and prostate cancer [9].

Good knowledge, attitudes, and practices regarding foot care are crucial in preventing foot ulcers in diabetes [10]. Prevention strategies acknowledge the importance of patient health education. It is believed that through patient education, individuals can improve their knowledge about diabetes-related foot problems, adopt better foot care practices, and consequently reduce foot complications [6]. Effective foot care education and a multidisciplinary approach can reduce diabetic foot ulcers and amputations by up to 85% [2].

One of the efforts to prevent diabetic foot problems is to meet the self-efficacy needs through diabetic foot care education [11]. Self-efficacy refers to an individual's belief in their ability to perform a specific behavior adequately [12]. In the context of diabetes, self-efficacy relates to the enhancement of self-care behaviors [13]. Self-care behaviors encompass the decisions and actions individuals take to manage their health problems [14]. Self-efficacy and self-care skills in diabetic patients can control the impact and complications of diabetes [15]. Additionally, foot care education is a suitable nursing intervention to increase patient knowledge and self-care practices [16].

Health Belief Model (HBM) serves as an effective framework for designing educational interventions and promoting preventive behaviors in the prevention and management of chronic diseases [17]. The HBM is noted for its applicability to self-care behaviors in patients with type 2 diabetes [18]. A systematic review shows that it plays an active role in diabetes management and prevention [19], identifying it as one of the most widely used models in health education and promotion [20].

It is also stated that the use of new training methods may be more effective than the use of traditional training systems [21]. The use of digital technology has been found to be particularly effective in health promotion and lifestyle changes among DM patients [22]. Web-based health education not only offers opportunities to improve diabetes self-care but also enhances patient engagement and clinical outcomes [23]. The International Diabetic Foot Study Group recommends that further research be conducted in methods and technologies to modify information and attitudes about foot care [24]. Additionally, studies indicate the need to pay more attention to the 'low-risk' patient group in terms of diabetic foot development [25].

In the literature, there are various studies on the effects of Health Belief Model (HBM) and web-based education methods on foot care knowledge, behaviour and self-efficacy of individuals with diabetes [26-29]. However, these studies have generally focused on high-risk patients, and there is a limited number of studies addressing the education of low-risk type 2 diabetic individuals on foot care [25]. This situation creates an important gap in the literature, because foot care education in low-risk individuals can play a major role in preventing complications (ulcers, amputations, etc.). This study aims to examine the effect of web-based education based on the health belief model on foot care knowledge, behaviour and self-efficacy in low-risk type 2 diabetic individuals who are likely to experience diabetic foot problems (ulcer, amputation, etc.). In this context, it is assumed that web-based diabetic foot care training based on the Health Belief Model will fulfil the following hypotheses in individuals with diabetes who are unlikely to have diabetic foot problems:

H1a: The knowledge of diabetic foot care will increase in the experimental group compared to the control group.

H1b: The foot care behaviours of the individuals in the experimental group will increase compared to the control group.

H1c: Self-efficacy level of individuals in the experimental group will increase in foot care compared to the control group.

METHOD

Study Design

This study is a randomized controlled experimental trial. The research was conducted from December 2021 to May 2023 at Tuşba Family Health Center (FHC) No. 1, under the Van Provincial Health Directorate.

Participants

The study was conducted in a Family Health Centre (FHC) in Van province between December 2021 and May 2023. under Van Provincial Health Directorate. The population of the study consisted of 155 individuals who met the inclusion criteria among 1008 individuals registered to this FHC and diagnosed with type 2 diabetes. Convenience sampling method was used for sample selection and 142 individuals agreed to participate in the study. Power analysis method was used to determine the sample size of the study. In the power analysis using Cohen's standard effect sizes, it was determined that 128 people, 64 in each group, should be reached to reach 80% power at 0.5% effect size, 0.05% margin of error level and 0.95% confidence interval [30]. However, considering the possibility of sample loss in the study, 10% more than the calculated sample was included in the randomization process. Thus, the study was conducted with a total of 142 participants, 71 in the experimental group and 71 in the control group. The sample size was deemed sufficient to detect significant differences [30]. Participants were randomly assigned to either the experimental or control group using the "Random Allocation Software" developed by Saghaei [31]. Allocation was based on participant enrollment order and the software output. The randomization process followed CONSORT (2018) guidelines, as illustrated in the Randomisation Chart (Figure 1).

Inclusion Criteria:

- Type 2 diabetes diagnosed at least one year ago
- 18 to 65 years old,
- Literate
- Using a computer or smartphone,
- Those with internet access,
- Has not participated in diabetic foot care training before
- Physically, cognitively or mentally able to answer the questions
- People who are willing to participate.
- Low risk of developing foot ulcers
- No loss of normal protective sensation
- No foot deformity
- No previous history of foot ulcer

Exclusion Criteria:

- Individuals who did not meet the inclusion criteria,
- Those with diabetic foot complications
- Foot deformities, or any other medical condition that would prevent their participation were excluded.

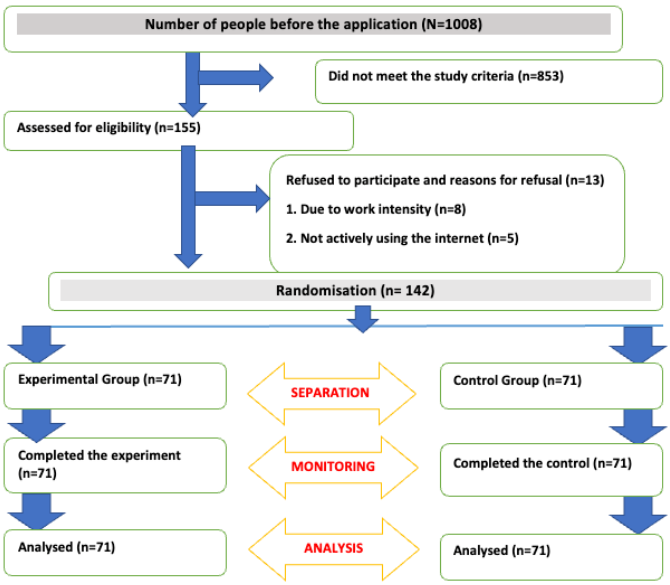

Figure 1. Consort 2018 flow diagram

Outcome Measures

Introductory Information Form: Prepared by the researchers based on a literature review [32,33]. The first section included descriptive characteristics of the participants such as age, gender, marital status, and education level. In the second part, twelve questions aimed to evaluate the participants' experiences and practices related to diabetes management, with a particular focus on foot care. These questions assessed factors such as the presence of other chronic diseases besides diabetes, types of treatment used (e.g. diet, oral medication, insulin), awareness of the impact of diabetes on foot health and regular foot checks, and seeking professional help.

Diabetic Foot Knowledge Scale (DFKS): A sub-dimension of the Diabetes Knowledge Questionnaire developed by Garcia et al. The Cronbach's alpha for the Diabetic Foot Knowledge Scale was 0.63 [34]. The Turkish version's reliability and validity were assessed by Biçer and Enç in 2011. The scale consists of five items scored as "yes," "no," and "don't know," with scores of 1 for correct answers and 0 for incorrect answers. The lowest possible score is 0, and the highest is 5. Cronbach's α value was found to be 0.58 [35]. The Cronbach's alpha for this study was 0.64 for the pretest and 0.62 for the posttest.

Foot Care Behavior Scale (FCBS): Created by Borges in 2007 to improve foot self-care behaviors in diabetes. Borges validated the scale with a podiatrist but did not conduct a reliability study [36]. The Turkish version's reliability and validity study was performed by Biçer and Enç in 2011. The scale consists of one dimension and 15 items, scored on a Likert scale from 1 (never) to 5 (always). The Cronbach's alpha was 0.83 in the Turkish study. The scale ranges from 15 to 75, with higher scores indicating better self-care behaviors [35]. The Cronbach's alpha in this study was 0.77 for the pretest and 0.76 for the posttest.

Diabetic Foot Care Self-Efficacy Scale (DFCSES): Developed by Bonnie Elliott Quarles in 2005, this scale assesses diabetic foot care self-efficacy using a Likert scale from 0 ("not at all adequate") to 10 ("very adequate") [37]. The Turkish version's reliability and validity study was carried out by Biçer and Enç in 2011. The scale includes 9 items with a maximum score of 90. The Cronbach's alpha was 0.86 in the Turkish study [35]. The Cronbach's alpha for this study was 0.79 for both pretest and posttest.his form, which was prepared by the researchers to determine the participants' sociodemographic characteristics, consists of a total of 14 questions [5,8,10].

Intervention

WEB EDUCATION DIAGRAM

Phase	Experimental Group	Control Group
Participant Assignment	"Random Allocation Software" program was used to assign participants to groups	"Random Allocation Software" program was used to assign participants to groups
↓		
Pre-Test Data Collection	Pre-test data were collected through face-to-face interviews in June and July 2022.	Pre-test data were collected through face-to-face interviews in June and July 2022.
↓		
Website Introduction	Participants were instructed on using the website https://dabe2022.atauni.edu.tr/, accessing training modules, and content update frequency.	The control group was only provided with contact information and no further intervention was made.
↓		
Training Content Development	The content was developed based on the Health Belief Model (HBM) with guidance from three subject matter experts.	Not applicable.
↓		
Training Topics	1. Definition and Importance of Type 2 Diabetes 2. Diabetic Foot Complications 3. Prevention Methods 4. Risks and Barriers 5. Self-Efficacy	Not applicable.
↓		
Training Duration	Conducted over 3 months, with one topic addressed every two weeks.	Not applicable.
↓		
WhatsApp Informational Messages	Bi-weekly informational messages sent via WhatsApp Web.	Not applicable.
↓		
Zoom Meetings	Two sessions held during the three-month period for Q&A and introductions.	Not applicable.
↓		
Monthly Reminders and Notifications	Monthly informational messages sent to encourage website engagement.	Not applicable.
↓		
Post-Test	Collected through face-to-face interviews in December 2022-January 2023.	Collected through face-to-face interviews in December 2022-January 2023.

Data Collection

Before starting the study, interviews were conducted with family physicians working in the family health center (FHC) where the study would be conducted in the last week of May 2022. A total of 8 family physicians work in the ASM in question. Family physicians were informed about the study. In addition, they were informed about the inclusion and exclusion criteria and their support was obtained in the process of determining the people to be included in the study. With the help of family physicians, data such as age, educational status and contact information of individuals with type 2 diabetes were accessed through the system in the first week of June 2022. Individuals who met the exclusion criteria were identified and excluded from the process. Individuals who met the age and education criteria were listed and the

researcher Y.S. started to call them by phone as of June 6, 2022. Individuals who did not respond to the first and second calls were considered as exclusion criteria by the researcher. The researcher made these calls systematically and efficiently by spreading these calls over certain time periods on a daily basis. During the phone calls, he introduced himself, gave brief information about the study and invited the individuals to the ASM for further evaluations. The researcher was present at the ASM during working hours four days a week (Monday, Tuesday, Thursday and Friday) throughout June and July 2022 to provide flexibility for the participants. Individuals who came to the FHC were reassessed by the researcher according to the inclusion and exclusion criteria. Individuals who met the criteria and agreed to participate in the study were divided into experimental and control groups according to the output obtained from the "Random Allocation Software" program and the order of arrival at the ASM. Pretests were administered to the individuals who agreed to participate in the study by face-to-face interview method. This process started on June 6, 2022 and was completed on July 29, 2022.

Ethical Approval

Approval was obtained from Atatürk University Faculty of Nursing Ethics Committee (date:11.05.2021, approval number: 2021-5/9). Approval was obtained from Van Provincial Health Directorate (E-73040253-129) to conduct the study in Van Tuşba Family Health Center No. 1 Patients enrolled in the study in the experimental and control groups gave written and verbal informed consent. It was also emphasized that participation would not cause any harm and was entirely voluntary. The Helsinki Declaration of Human Rights was adhered to and the protection of individual rights was prioritized. Participants gave their consent based on this information. The study was registered in ClinicalTrials.gov (NCT05395442).

Statistical Analysis

The SPSS statistical programme (SPSS-25) was utilized to analyze the data obtained in this study. The data were analysed using numbers, percentages, min/max values, mean and standard deviation. For determining the normal distribution, kurtosis-skewness value was analyzed. According to the result of the kurtosis-skewness value, the normal distribution of the data (+1.5,-1.5) was determined [38]. Cronbach-α number was used to determine the reliability of the measurement tools, categorical variables were analyzed using chi-square, Fisher-Freeman-Halton Exact Test and Fisher Halton Exact Test to determine the homogeneity of the experimental and control groups, Paired Samples t test was used to compare individuals within groups and Independent Samples t test was used to compare individuals between groups. The study accepted $p<0.05$ as statistically significant.

RESULTS

It was determined that 53.5% of the individuals with type 2 diabetes in the experimental group, who were less likely to have diabetic foot problems, were male, 83.1% were married, 31.0% were secondary education graduates, 50.7% had income less than expenses, 64.8% were non-smokers and 46.5% had a Body Mass Index between 18.50-24.99. Furthermore, the mean age was 46.59±11.82 years, the mean HbA1c was 8.47±2.36, and the mean duration of diagnosis was 7.35±6.28 years. In the control group, which was lower probability of having diabetic foot problems, 53.5% were female, 83.1% were married, 31.0% were primary school graduates, 57.7% had income below the expenditure level, 76.1% were non-smokers and 49.3% had a Body Mass Index between 18.50-24.99. Furthermore, the mean age was 47.10±11.36 years, the mean HbA1c was 8.18±2.04 and the mean duration of diagnosis was 6.46±6.19 years. Low-risk type 2 diabetic individuals in the experimental and control groups were found to be homogeneous in terms of their identifying characteristics ($p>0.05$) (Table 1).

When evaluated in terms of disease-related variables, 56.3% of the individuals in the experimental group did not have any other chronic disease other than diabetes, 53.5% had diabetes treatment in the form of oral antidiabetics, 60.6% had information about the damages caused by diabetes to their feet, 80.3% had not had their feet examined before due to DM, 77.5% did not have information about diabetic foot care, 85.9% did not have regular foot care examinations, 80. 3% did not have their feet examined by doctors or other healthcare professionals, 97.2% did not have any problems that prevented foot care, 40.8% did not check their feet for temperature, humidity, redness, wounds, discharge and calluses every day, 88.7% did not receive support while performing foot care examinations on their own, and 69.0% paid attention to shoes, socks and personal care due to DM. When evaluated in terms of disease-related variables, 47.9% of the individuals in the control group did not have any other chronic disease other than diabetes, 39.4% had diabetes treatment in the form of oral antidiabetics, 66.2% had information about the damages caused by diabetes to their feet, It was determined that 84.5% had not had their feet examined before due to DM, 76.1% did not have information about diabetic foot care, 77.5% did not have regular foot care examinations, 80.3% did not have their feet examined by doctors or other healthcare professionals. It was determined that 3% did not have foot examinations by doctors or other healthcare professionals, 97.2% did not have any problems that prevented foot care, 45.1% did not check their feet for temperature, humidity, redness, wounds, discharge and calluses every day, 88.7% did not receive support while performing foot care examinations on their own, and 69.0% paid attention to shoes, socks and personal care due to DM. Individuals with low-risk type 2 diabetes in both experimental and control groups were homogeneous in terms of disease-related descriptive characteristics ($p>0.05$) (Table 2).

When comparing the pretest scores of individuals with low-risk type 2 diabetes in the experimental and control groups, no statistically significant differences were found. For the Diabetic Foot Knowledge Scale (DFKS), the mean score was 1.35 (SD=1.51) in the experimental group and 1.15 (SD=1.27) in the control group, with no significant difference observed ($t=-0.841$, $p=0.402$). Similarly, no significant differences were found for the Foot Care Behavior Scale (FCBS) and Diabetic Foot Care Self-Efficacy Scale (DFCSES), with $t=1.557$, $p=0.122$ and $t=1.167$, $p=0.245$, respectively (Table 3).

According to the post-test results of individuals with low-risk type 2 diabetes, the experimental group showed significant improvements across all measurements compared to the control group. For the Diabetic Foot Knowledge Scale (DFKS), the mean score in the experimental group was 3.01 (SD=3.34), while in the control group it was 1.33 (SD=1.28), and this difference was statistically significant ($t=7.582$, $p=0.001$). For the Foot Care Behaviour Scale (FCBS), the mean score in the experimental group was 51.14 (SD=8.58), and in the control group it was 46.73 (SD=8.22), with a significant difference ($t=3.125$, $p=0.002$). The Diabetic Foot Care Self-Efficacy Scale (DFCSES) scores were 70.28 (SD=9.77) in the experimental group and 62.40 (SD=11.76) in the control group, with a significant difference ($t=4.337$, $p=0.001$) (Table 4).

When comparing the pre-test and post-test mean scores within the groups of individuals with low-risk type 2 diabetes, the experimental group showed significant improvements across all measurements. For the DFKS, the pre-test mean was 1.35 (SD=1.51), and the post-test mean was 3.01 (SD=3.34), with a statistically significant difference ($t=-7.382$, $p=0.001$). For the FCBS, the pre-test mean was 47.63 (SD=10.44), and the post-test mean was 51.14 (SD=8.58), with a significant difference ($t=-2.100$, $p=0.039$). For the DFCSES, the pre-test mean was 62.36 (SD=16.66), and the post-test mean was 70.28 (SD=9.77), with a significant difference ($t=-3.198$, $p=0.002$). In contrast, no significant changes were observed in the DFKS, FCBS, or DFCSES scores in the control group (Table 5).

Table 1. Comparison of control variables of individuals with low-risk type 2 diabetes in the experimental and control groups (n=142)

Variables		Experimental Group (n=71)		Control Group (n=71)		Test and p
		n	%	n	%	
Gender	Female	33	46.5	38	53.5	χ2= 0.704* p= 0.401
	Male	38	53.5	33	46.5	
Marital Status	Married	59	83.1	59	83.1	χ2= 0.000* p= 1.000
	Single	12	16.9	12	16.9	
Education Level	Literate	12	16.9	13	18.2	χ2= 0.660* p= 0.883
	Primary education	19	26.7	22	31.0	
	Secondary Education	22	31.0	18	25.4	
	University	18	25.4	18	25.4	
Income Status	Income< Expenditure	36	50.7	41	57.7	χ2= 0.800** p= 0.714
	Income= Expenditure	31	43.7	27	38.0	
	Income> Expenditure	4	5.6	3	4.3	
Smoking status	Yes	25	35.2	17	23.9	χ2= 2.164* p= 0.141
	No	46	64.8	54	76.1	
Body Mass Index	<18.50	2	2.8	1	1.4	χ2= 0.888** p= 0.844
	18.50-24.99	33	46.5	35	49.3	
	25.0-29.99	28	39.4	25	35.2	
	30.0-34.99	8	11.3	10	14.1	

Chi-square test,Fisher-Freeman-Halton Exact Test,*** Fisher Halton Exact Test*

Table 2. Comparison of disease-related control variables of individuals with low-risk type 2 diabetes in the experimental and control groups (n=142)

Variables		Experimental Group (n=71)		Control Group (n=71)		Test and p
		n	%	n	%	
A chronic disease other than diabetes mellitus	There is	31	43.7	37	52.1	χ2= 1.016* p= 0.313
	None	40	56.3	34	47.9	
Treatment in diabetes	Diet only	10	14.1	14	19.7	χ2= 6.329* p= 0.097
	Oral antidiabetic	38	53.5	28	39.4	
	Insulin only (injections)	17	23.9	14	19.7	
	Oral antidiabetic and insulin	6	8.5	15	21.2	
Knowledge about the effects of diabetes on your feet	Yes	43	60.6	47	66.2	χ2= 0.485* p= 0.486
	No	28	39.4	24	33.8	
Previous examination of the foot due to DM	Yes	14	19.7	11	5.5	χ2= 0.437* p= 0.509
	No	57	80.3	60	84.5	
Knowledge about diabetic foot care	There is	16	22.5	17	23.9	χ2= 0.039* p= 0.843
	None	55	77.5	54	76.1	
Regularly performing foot care examinations	Yes	10	14.1	16	22.5	χ2= 1.695* p= 0.193
	No	61	85.9	55	77.5	
Previous foot examination by a doctor or other health professionals	Yes	14	19.7	14	19.7	χ2= 0.000* p= 1.000
	No	57	80.3	57	80.3	
Any problem condition that prevents foot care	Yes	2	2.8	2	2.8	χ2= 0.690* p= 1.000
	No	69	97.2	69	97.2	
Check your feet daily for temperature, humidity, redness, sores, discharge and calluses	Yes	42	59.2	39	54.9	χ2= 0.259* p= 0.611
	No	29	40.8	32	45.1	
Receiving support when performing a foot care examination by yourself	Yes	8	11.3	8	11.3	χ2= 0.000* p= 1.000
	No	63	88.7	63	88.7	
Paying attention to shoes, socks and personal care due to DM	Yes	49	69.0	49	69.0	χ2= 0.000* p= 1.000
	No	22	31.0	22	31.0	

Chi-square Test,Fisher-Freeman-Halton Exact Test,*** Fisher Halton Exact Test*

Table 3. Comparison of mean pretest scores of DFKS, FCBS, and DFCSES in low-risk type 2 diabetes individuals in experimental and control groups (n=142)

Variable	Experimental Group (n=71)		Control Group (n=71)		Test and p
	Mean	SD	Mean	SD	
Diabetic Foot Knowledge Scale	1.35	1.51	1.15	1.27	t=-0.841* p=0.402
Foot Care Behaviour Scale	47.63	10.44	44.85	10.79	t=1.557* p=0.122
Diabetic Foot Care Self-Efficacy Scale	62.36	16.66	59.45	12.84	t=1.167* p=0.245

**Independent Samples t testi*

Table 4. Intergroup comparison of DFKS, FCBS and DFCSES posttest mean scores of individuals with low-risk type 2 diabetes in the experimental and control groups (n=142)

Variable	Experimental Group (n=71)		Control Group (n=71)		Test and p
	Mean	SD	Mean	SD	
Diabetic Foot Knowledge Scale	3.01	3.34	1.33	1.28	t=7.582* p=0.001
Foot Care Behaviour Scale	51.14	8.58	46.73	8.22	t=3.125* p=0.002
Diabetic Foot Care Self-Efficacy Scale	70.28	9.77	62.40	11.76	t=4.337* p=0.001

**Independent Samples t testi*

Table 5. In-group comparison of pre and post-test mean scores of individuals with low-risk type 2 diabetes in the experimental and control groups (n=142)

Scales	Experimental Group (n=71)		Test and p	Control Group (n=71)		Test and p
	Pre-test Score Mean ± SD	Post Test Score Mean±SD		Pre-Test Score Mean ±SD	Post Test Score Mean±SD	
Diabetic Foot Knowledge Scale	1.35±1.51	3.01±3.34	t =-7.382 p =0.001*	1.15±1.27	1.33±1.28	t =-0.839 p =0.404
Foot Care Behaviour Scale	47.63±10.44	51.14±8.58	t =-2.100 p =0.039*	44.85±10.79	46.73±8.22	t =-1.121 p =0.266
Diabetic Foot Care Self-Efficacy Scale	62.36±16.66	70.28±9.77	t =-3.198 p =0.002*	59.45±12.84	62.40±11.76	t =-1.456 p =0.150

**Paired Samples t testi*

DISCUSSION

This study found that the experimental group, which received diabetic foot care education, showed significant improvements in knowledge, behavior, and self-efficacy compared to the control group. After the educational intervention, the experimental group scored higher on the DFKS, FCBS, and DFCSES, while no changes were observed in the control group. These findings highlight the effectiveness of diabetic foot care education in improving knowledge and care behaviors, emphasizing its crucial role in preventing diabetes-related complications.

This study evaluated the impact of web-based education on diabetic foot care, structured around the sub-dimensions of the Health Belief Model (HBM) sensitivity, severity, benefit, barrier, and self-efficacy perception. The findings indicate a significant increase in knowledge levels regarding diabetic foot care among individuals in the experimental group who received the web-based education. In contrast, no such increase was observed in the control group. This result is consistent with literature suggesting that education based on HBM can substantially enhance knowledge, attitudes, and self-care behaviors in type 2 diabetes patients [27]. Previous studies also support this, showing that diabetic foot care education programs significantly improve foot care knowledge [35]. The web-based approach of this study contributed to a significant increase in knowledge levels due to its cross-device accessibility, no login required, and inclusion of the Health Belief Model (HBM) sub-dimensions. These factors enabled the training to reach a wider audience and users to easily access the training materials. This finding supports hypothesis H1a that web-based education has a positive effect on the diabetic foot care knowledge of individuals with low risk of diabetic foot problems. Web-based education programs can play a critical role in diabetes management by increasing individuals' knowledge and awareness levels and preventing diabetic foot complications. This is a result that emphasizes the importance of innovative and accessible educational methods in diabetes management.

Improving self-efficacy through diabetic foot care education is crucial for preventing diabetic foot problems [11]. Self-efficacy is linked to better self-care behaviors and is a significant factor influencing mortality rates in diabetic patients [13,14]. Research has identified self-efficacy as a critical determinant of self-care behaviors in diabetes patients [39]. Enhanced self-efficacy and self-care skills can help manage the effects and complications of diabetes [15]. The study demonstrated that the web-based education significantly improved foot care practices and self-efficacy in the experimental group. Similar results were found in randomized controlled trials showing significant improvements in knowledge, self-efficacy, and foot care behaviors following animated mobile diabetic foot care education [40]. In an experimental study, it was found that patient education positively affected foot care behaviours and self-efficacy levels [35]. The study supported hypotheses H1b and H1c by showing that web-based training significantly improved foot care practices and self-efficacy in individuals with type 2 diabetes. The comprehensive content of the training increased participants' knowledge and improved their perception of the sensitivity and severity of the disease. As a result, participants in the experimental group who were low likely to experience diabetic foot problems became more knowledgeable and confident in foot care practices. This suggests that web-based health belief model training is an effective tool in diabetes management and contributes to better prevention of diabetic foot complications.

The strengths of this study include its randomized controlled design and robust methodological foundation provided by a comprehensive web-based education program. The Health Belief Model-based training facilitated effective information delivery, and interactive tools like Zoom meetings supported active participant engagement in the educational process.

Limitations

Limitations of this study include the fact that the study was conducted in a single province, the results can only be generalized to this group and the lack of sustainability of the website.

CONCLUSION

These findings indicate that participants with type 2 diabetes who are low likelihood of experiencing diabetic foot problems in both the experimental and control groups were homogeneous in terms of their descriptive characteristics. The significant increase in DFCS, FCBS, and DFCSES scores in the experimental group suggests that the intervention had a positive impact on diabetes management and self-efficacy for individuals with type 2 diabetes who are low likely to experience diabetic foot problems. Based on these results, healthcare professionals should consider implementing similar interventions to improve diabetes management and enhance the quality of life of individuals with type 2 diabetes who are low likely to experience diabetic foot problems.

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INVESTIGATION OF THE EFFECT OF DIFFERENT TYPES OF INSOLES ON ELECTROMYOGRAPHIC MUSCLE ACTIVATION IN INDIVIDUALS WITH PES PLANUS

PES PLANUSLU BİREYLERİN FARKLI TİPTEKİ TABANLIKLARININ ELEKTROMYOGRAFİK KAS AKTİVASYONU ÜZERİNE ETKİSİNİN İNCELENMESİ

Ebrar Erkan[1], Tamer Çankaya[2*]

[1]Institute of Health Sciences, Bolu Abant İzzet Baysal University, Bolu, Türkiye

[2]Department of Physiotherapy and Rehabilitation, Faculty of Health Sciences, Bolu Abant İzzet Baysal University, Türkiye

ABSTRACT

Objective: The aim of this study is to examine the effect of prefabricated insoles made of different materials on lower extremity muscle activity in individuals with pes planus and to investigate whether it changes towards the pattern seen in people with normal foot arch.

Method: Six individuals with flexible pes planus participated voluntarily in this descriptive and correlational study. The mean age of the individuals was 33.8±11.1 years, height 1.64±0.06 m, mean weight 62.3±7.3 kg, mean Body Mass Index (BMI) 23.1±2.7 kg/m^2. Pes planus severity of individuals was measured with Foot Posture Index (FPI) and Clarke angle using podoscope device and footprint method. Activation of the muscles was measured with a surface electromyography (sEMG) device for maximum isometric contraction (MIC) and during walking without insoles, soft (silicone), semi-rigid (polyform) and rigid (steel) insoles at one-day intervals.

Results: No significant difference in %MIC values was observed among the insoles, soft (silicone), semi-rigid (polyform) and rigid (steel) insoles within the same phase of gait ($p>.05$). A significant difference was found between the heel strike (0-10%) phase of gait and the swing (60-100%) phases of gait in terms of %MIC value in the electromyography (EMG) measurement taken from the tibialis anterior muscle with a rigid (steel) insole ($p<.05$). In the EMG measurement taken from the peroneus longus muscle with a semirigid (polyform) insole, a significant difference was found between the mid-stance (10%-40%) phase of the gait and the swing (60-100%) phases in terms of %MIC value ($p<.05$).

Conclusion: While rigid (steel) insoles reduce tibialis anterior muscle activation in heel strike phase compared to swing phase, semirigid (polyform) insoles increase peroneus longus muscle activation in mid-stance phase of gait compared to swing phase.

Key Words: Pes planus, Flat feet, Insole, Muscle activity

ÖZ

Amaç: Bu çalışmanın amacı pes planuslu bireylerde değişik materyallerden üretilmiş prefabrikasyon tabanlıkların alt ekstremite kas aktivitesi üzerine etkisini incelemek ve normal ayak arkı olan kişilerde görülen paterne doğru değiştirip değiştirmediğini araştırmaktır.

Yöntem: Tanımlayıcı ve korelasyonel olarak yapılan bu çalışmaya esnek pes planusa sahip 6 birey gönüllü olarak dahil oldu. Bireylerin yaş ortalamaları 33.8±11.1 yıl, boy ortalamaları 1.64±0.06 m, kilo ortalamaları 62.3±7.3 kg, vücut kitle indeksi (VKİ) ortalamaları 23.1±2.7 kg/m^2 olarak bulundu. Bireylerin pes planus şiddeti podoskop cihazı ve ayak izi yöntemiyle Clark açısı hesaplanarak ve Ayak Postür İndeksi (APİ) ile ölçüldü. Kas aktivasyonu yüzeyel elektromiyografi (yEMG) cihazı ile maksimum izometrik kontraksiyon (MİK) ve yürüyüş sırasında tabanlıksız, soft (silikon), semirijit (poliform) ve rijit (çelik) tabanlıklar ile birer gün aralıkla ölçüldü.

Bulgular: Tabanlıksız, soft (silikon), semirijit (poliform) ve rijit (çelik) tabanlıklar arasında yürüyüşün aynı fazında %MİK değerlerinde farklılık gözlemlenmedi ($p>.05$). Tibialis anterior kasından rijit (çelik) tabanlıkla alınan elektromiyografi (EMG) ölçümünde, %MİK değeri açısından yürüyüşün topuk vuruşu (0-%10) fazı ile sallanma (%60-%100) fazları arasında anlamlı bir fark saptandı ($p<.05$). Peroneus longus kasından semirijit (poliform) tabanlıkla alınan EMG ölçümünde %MİK değeri açısından yürüyüşün orta duruş (%10-%40) fazı ile sallanma (%60-100) fazları arasında anlamlı bir fark saptandı ($p<.05$).

Sonuç: Rijit (çelik) tabanlık topuk vuruşu fazında sallanma fazına kıyasla tibialis anterior kas aktivasyonunu düşürürken, semirijit (polyform) tabanlık yürüyüşün orta duruş fazında sallanma fazına kıyasla peroneus longus kas aktivasyonunu arttırmaktadır.

Anahtar Kelimeler: Pes planus, Düztaban, Tabanlık, Kas aktivasyonu

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***Corresponding author/Sorumlu yazar:** Bolu Abant İzzet Baysal University, Faculty of Health Sciences, Department of Physiotherapy and Rehabilitation, Bolu, Türkiye
[2*]Email: tamercankaya@hotmail.com, [1]Email: erkanebr@gmail.com

INTRODUCTION

Pes planus is defined as the loss of the medial longitudinal arch (MLA) height of the foot during weight bearing or abnormally low arch height [1]. Whether it is a congenital or acquired condition, it has features such as talus medial rotation, decreased medial arch height, and forefoot supination and abduction [2]. Although the exact cause of pes planus has not been determined, genetic factors, acquired factors, paralysis, pronated foot or obesity can cause pes planus [3]. Its true prevalence is uncertain due to the lack of precise clinical or radiographic criteria to define pes planus. However, in the adult population, studies by different investigators have reported a prevalence of approximately 5 to 14% [4,5] and it presents as an incidental finding or a symptomatic condition with variable clinical consequences ranging from mild limitations to pain leading to severe disability [6].

The medial longitudinal arch of the foot is associated with shock absorption and force transmission during standing and walking [7]. Due to pes planus, the load on the foot cannot be distributed properly and this alters the muscle activity of the intrinsic and extrinsic muscles [8]. Studies have reported that lower extremity muscle activity due to pes planus is higher or lower than that of the normal foot during gait or standing on one leg [9,10].

Conditions caused by pes planus are usually treated using some form of orthotic device. Today, there are many types in terms of measurement, design, material used and the type of production, including custom made or prefabricated. Such devices are designed to provide stability and realign the arch of the foot and have had significant success in alleviating patients' symptoms [11-13]. However, there is no consensus on the material of the insoles to be used in the treatment of pes planus.

The aim of this study was to investigate the effect of prefabricated insoles made of different materials on lower extremity muscle activation in individuals with pes planus. Our hypothesis is that the material factor to be used will change muscle activation in individuals with pes planus. When the existing literature is examined, it is seen that the effect of insoles made of different materials on muscle activity in individuals with pes planus remains unclear. Therefore, we think that analysing the EMG data during walking by dividing the data into gait phases will clarify which muscle pattern is affected by the material factor of the insoles when evaluating the effectiveness of insoles made of different materials (soft, semirigid and rigid) on muscle activation. In addition, comparing the data obtained from our study with the information in the literature regarding the muscle pattern during the phases of gait in individuals with normal foot arch will contribute to the evaluation of the effectiveness of the material factor selection in the correction of the muscle pattern and will fill the gap in the literature on this subject.

METHOD

Study Design

We conducted a descriptive and correlational study to examine the effect of insoles made of different materials on lower extremity muscle activity in individuals with pes planus.

Participants

The inclusion criteria of the individuals were willingness to participate in the study, Foot Posture Index (FPI) used in the evaluation of pes planus to be +6 and above [14,15] and Clarke angle calculated by the footprint method to be below 41° [15,16]; Exclusion criteria were as follows: cardiovascular and inflammatory diseases, neurologic deficits, systemic diseases affecting the foot, pregnancy, history of spine and lower extremity surgery, leg discrepancy of more than 5mm, rigid pes planus, use of insoles in the last 12 months.

Individuals were interviewed face to face for foot posture analysis. Those who agreed to participate in the study were informed about the study and signed a written consent form.

The study was conducted at Bolu Abant İzzet Baysal University, Faculty of Health Sciences, Department of Physiotherapy and Rehabilitation. The sample of the study was selected through random sampling. The number of individuals with pes planus to be included in the study was determined by performing power analysis with G*Power 3.1 software over the insoles variables used in repeated measurements in individuals with pes planus in accordance with the purpose of the study. In this study, the effect size α=0.05 was taken and when power analysis was performed at 80% power and 80% confidence interval, the number of samples required for the study was determined to be 6 individuals [17]. However, since only individuals with pes planus would participate in the study, the study was started with 20 individuals, taking into account situations such as those who did not have pes planus, who could not participate in any measurement in repeated measurements or who wanted to leave at any stage of the study. One of the participants was found to have used insoles in the last 12 months and was excluded from the study. According to foot posture evaluation, 8 people were found to have pes planus. 2 people who did not want to continue the study voluntarily left the study. The evaluation form was filled out with the remaining 6 people and the study was completed with 6 female individuals, with a mean age of 33.8±11.1 years, mean height of 1.64±0.06 m, mean weight of 62.3±7.3 kg, mean body mass index (BMI) of 23.1±2.7 kg/m².

Insoles

In the study, 3 prefabricated insoles were used: soft (silicone), semirigid (polyform) and rigid (steel). Among the insoles available for all shoe sizes, those that matched the participants' own shoe size were selected.

Each type of insoles had medial and transverse arch supports. Soft insoles were made of 100% silicone (Figure 1). Semirigid insoles consisted of polyform arch support on 1mm thermoplastic material (Figure 2). The rigid insoles had a steel medial arch support and were covered with leather (Figure 3). To ensure standardization, all insoles of different materials had equal medial arch height.

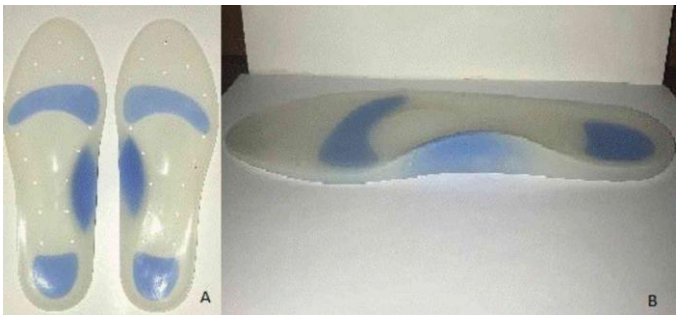

Figure 1. Top (A) and side views (B) of the soft (silicone) insole.

Figure 2. Top (A) and side views (B) of semirigid (polyform) insole

Figure 3. Top (A) and side views (B) of Rigid (steel) insole.

Outcome Measures

Foot posture was determined using the footprint method and Foot Posture Index (Foot Posture Index-6). We used podoscope in the footprint method. When we did not have the opportunity to use the podoscope device because it was shared with other researchers in the faculty, we used the trace of the powdered foot on black cardboard, which is similar to the podoscope measurement method and is a suitable method for evaluating foot arches [18]. In the footprint method, the Clarke angle was determined from the photograph taken of the individuals participating in the study while they were on the podoscope (Quirumed, Inc, Spain) or from the trace of the powdered foot on black cardboard while standing still. Angle Meter application (IOS) was used to determine the angle.

A different day was planned for the experimental study in which electromyography (EMG) would be measured. Muscle activation measurements of the individuals were completed with a Delsys Trigno Wireless System superficial EMG device (sample rate 2000 Hertz, transmittance band 20-450 Hertz and average noise cancellation rate >80 decibels (dB), (Delsys, Inc, USA).

Measurements were performed during maximum isometric contraction (MIC) and muscle function (gait). Before the sensors and electrodes were placed on the individual's leg, the area was shaved and thoroughly cleaned with alcohol cotton wool until slight redness was observed. The sensors were fixed to the leg with rigid tape. Silver/silver chloride (Ag/AgCI) bipolar sEMG electrodes (3.7cm x 3.3cm) were used with a distance of 2 cm between each other. The electrodes were placed parallel to the direction of muscle fiber extension, controlled by palpation and in accordance with SENIAM protocols. Measurements were performed on the dominant legs of the individuals. The signals received during the measurements were checked on the screen of the computer used and when artifacts occurred, the measurement was stopped to check the electrodes and sensors. Before starting the measurements, explanations were given to the individuals about the movements they were asked to perform during MIC. For MIC measurements, individuals were positioned as in SENIAM protocols and maximum resistance was applied for 5 s. Each measurement was repeated 3 times and the mean value of 3 measurements was taken. A one-minute rest period was given for each muscle group to prevent muscle fatigue.

EMG muscle activation of the individuals participating in the study was measured 4 times in total during walking, without insoles and with 3 different insoles: soft (silicone), semirigid (polyform) and rigid (steel) insoles. The design and material of the insoles were the same for each participant and insoles were selected in randomized order.

The gait analysis was started without insoles and the study was completed in 3 days with a one-day break between measurements taken with insoles. A metronome was used to standardize the gait speed and was set to 109 steps per minute [19]. A trial walk was performed for the individuals to get used to the rhythm. Afterwards, they were asked to take 5 steps starting with the dominant foot. All measurements were made with a comfortable, fixed sneaker belonging to the individual.

EMG Data Analysis

The recorded EMG signals were analyzed with the Delsys Analysis System 4.5.0 application.

For the analysis of the individual who was asked to isometrically contract the relevant muscle for 5 seconds, the signals released during the middle 3 seconds were taken into consideration and the value was recorded in microvolts (µV). The mean values obtained in the analysis of the MIC repeated 3 times for each muscle was used in the calculation of %MIC. The raw signals were cleaned of motion artifact with a 20-500 bandpass filter and the root mean square values (RMS) were calculated at 0.1 s intervals.

After 20-500 bandpass filtering of the raw data, RMS values were calculated at 0.1-second intervals and recorded in microvolts (µV) [20,21]. The stride used for the analysis was divided into phases of the gait by dividing it into parts based on duration. Accordingly, heel strike between 0 and 10%, mid-stance between 10%-40%, push-off phase between 40-60% and swing phase between 60-100% were divided into 4 parts (Figure 4) [3]. The following equation was used to normalize the muscle activation value:

%MIC (during muscle activity) = (RMS (µV)/MIC (µV))*100 [22].

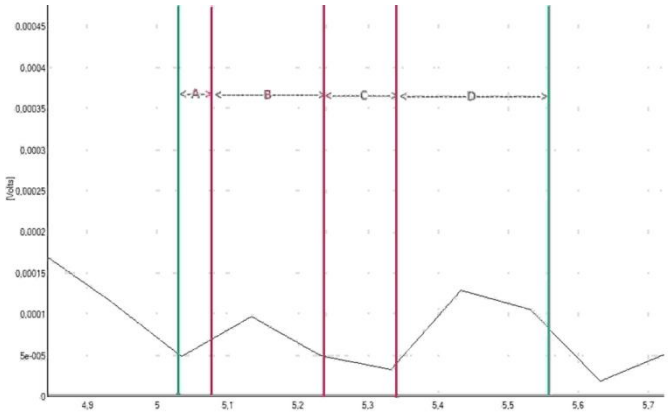

Figure 4. EMG data obtained from the tibialis anterior muscle divided into walking phases: A: Heel strike B: Mid-stance C: Push-off D: Swing

Ethical Approval

Approval for the study was obtained on 16.03.2021 and with the number 2021/73 from Bolu Abant Izzet Baysal University Clinical Research Ethics Committee.

Statistical Analysis

The conformity of the data to normal distribution was evaluated by Histogram, Q-Q graphs and Shapiro-Wilk test. Friedman's analysis was used in the evaluation of repeated measurements of insoles material variables. Dunn's test was used for multiple comparisons. The relationship between quantitative data was evaluated by Spearman correlation analysis. Data analysis was performed in R 4.2.2 (www.r-project.org) program and Turcosa Cloud (Turcosa Ltd Co) statistical software. Significance value was accepted as $p<.05$.

RESULTS

In the evaluation of the severity of pes planus, the frequency and mean Clarke angle and FPI values specific to the dominant and nondominant foot were calculated. Accordingly, the dominant foot Clarke angle was found to be 24.5±4.9 degrees and the nondominant Clarke angle 17.8±8 degrees. Dominant foot FPI score was 11±0.6 and nondominant FPI was 8.8±1.4. The mean %MIC values of tibialis anterior, peroneus longus, gastrocnemius medialis and soleus muscles in different phases of gait were compared in repeated EMG measurements without insoles and with 3 different insoles.

While there was no statistically significant difference between the gait phases in the EMG measurements obtained from the tibialis anterior muscle without insoles, with soft (silicone) and semirigid (polyform) insoles (p>.05), there was a significant difference between the 0-10% and 60-100% phases of gait in terms of %MIC value in the EMG measurement obtained with rigid (steel) insoles (p<.05) (Table 1).

In the EMG measurements obtained from the peroneus longus muscle without insoles, with soft (silicone) and rigid (steel) insoles, there was no statistically significant difference between the gait phases in terms of %MIC value (p>.05), while in the EMG measurement obtained with semirigid (polyform) insoles, a significant difference was found between the 10-40% and 60-100% phases of gait in terms of %MIC value (p=.042). There was no significant difference between the %MIC values of no insoles, soft (silicone), semirigid (polyform) and rigid (steel) insoles in the same phase of gait (p>.05) (Table 2).

In the EMG measurements obtained from the gastrocnemius medialis and soleus muscle without insoles, with soft (silicone), semirigid (polyform) and rigid (steel) insoles, there was no statistically significant difference in %MIC values between gait phases (p>.05).

Table 1. Comparison of tibialis anterior muscle function with and without insoles and between percentile phases of gait and within each phase

	Percentage Phases of Walking				
Variables	**0-10%**	**10%-40%**	**40%-60%**	**60%-100%**	**P**
No insole	35.0(12.4-73.5)	43.0(16.7-77.3)	37.9(19.7-78.3)	30.5(22.7-53.2)	0.978
Soft (silicone)	37.2(15.0-58.0)	40.5(31.7-60.0)	26.0(15.0-35.9)	37.3(28.0-60.7)	0.457
Semirigid (polyform)	26.5(14.3-69.1)	33.5(15.1-73.9)	41.8(21.3-64.8)	39.7(31.0-53.0)	0.706
Rigid (steel)	3.5(0.0-26.9)^{a}	30.5(18.2-52.1)^{ab}	15.5(8.6-30.0)^{ab}	30.5(27.6-78.1)^{b}	**0.002**
p*	0.229	0.985	0.133	0.204	

Data are expressed as median (1st quartile-3rd quartile), p:Comparison results for each muscle according to walking phases, p:Comparison results for each walking phase according to insole types. Same letters in the same row indicate similarity of difference between phases, different letters indicate difference. Friedman analysis was used.*

Table 2. Comparison of peroneus longus muscle function between insole and without insole variables and between percentile phases of gait and within each phase.

	Percentage Phases of Walking				
Variables	**0-10%**	**10%-40%**	**40%-60%**	**60%-100%**	**p**
No insole	50.6(22.1-61.7)	68.0(34.8-95.2)	71.4(23.6-99.4)	53.8(26.4-96.5)	0.597
Soft (silicone)	50.4(4.5-71.3)	56.7(30.4-112.0)	30.4(15.4-56.3)	41.2(25.5-101.1)	0.241
Semirigid (polyform)	76.1(38.9-146.7)^{ab}	100.3(48.5-112.2)^{a}	40.7(21.0-117.0)^{ab}	56.0(16.5-82.4)^{b}	**0.042**
Rigid (steel)	14.3(0.0-56.0)	43.2(33.7-103.8)	62.5(24.9-108.1)	55.0(28.7-114.9)	0.597
p*	0.149	0.241	0.221	0.284	0.149

Data are expressed as median (1st quartile-3rd quartile, p:Comparison results for each muscle according to walking phase,. p:Comparison results for each walking phase according to insole types. Same letters in the same row indicate similarity of difference between phases, different letters indicate difference. Friedman analysis was used.*

DISCUSSION

In our study, the effect of prefabricated insoles of different materials on electromyographic muscle activation was investigated in individuals with pes planus. As a result of repeated measurements in which the effect of insoles of different materials on EMG in 4 phases of gait was examined, no significant difference was found between the %MIC values of insoles without insoles, soft (silicone), semirigid (polyform) and rigid (steel) insoles in the same phase of gait. There was no statistically significant difference in the %MIC values between the gait phases in the EMG measurements obtained from the gastrocnemius medialis and soleus muscles without insoles, with soft (silicone), semirigid (polyform) and rigid (steel) insoles. In the EMG muscle activation measurements obtained from the tibialis anterior muscle without insoles, with soft (silicone) and semirigid (polyform) insoles, there was no statistically significant difference between the gait phases in terms of %MIC value, while in the EMG measurement obtained with rigid (steel) insoles, it was observed that the tibialis anterior muscle function decreased in the heel strike (0-10%) phase of gait compared to the swing (60%-100%) phase. In the EMG measurements obtained from the peroneus longus muscle without insoles, with soft (silicone) and rigid (steel) insoles, there was no statistically significant difference between the gait phases in terms of %MIC value, while in the EMG measurement obtained with semirigid (polyform) insoles, it was found that peroneus longus muscle function increased in the mid-stance (10%-40%) phase of gait compared to the swinging (60%-100%) phase. When we compared the data we obtained with the literature information about the muscle pattern of the normal arch of the foot in these 4 phases of gait, polyform insoles increased peroneus longus muscle activation in the mid-stance phase compared to the swing phase as with the normal muscle pattern. Steel insoles reduced tibialis anterior muscle activation in the heel strike phase compared to the swing phase, and they distract muscle activation from the normal foot pattern during gait [3].

Pes planus may develop due to loss of strength and stability or overuse of the known extrinsic dynamic supporters of the MLA such as triceps surae, peroneus longus, tibialis posterior and anterior muscles [23,24]. EMG provides powerful information about neuromuscular function, provided appropriate signal processing is performed. Some studies have shown a decrease in strength and EMG amplitude in the muscles responsible for maintaining neutral foot posture [7,24]. Based on studies showing that the use of insoles can change the EMG amplitude in the stabilizer muscles of the foot, the use of the electromyographic evaluation method to evaluate muscle activation in our study seems to be appropriate for the purpose of the study [25-33]. Foot orthoses are widely used in the treatment of flexible pes planus. The evidence supporting this intervention was presented in 2 systematic reviews published in 2014 and 2021 [34,35], but the level of evidence on EMG muscle activation is unclear.

Our study has similar and different characteristics with other studies in terms of factors such as the stiffness of the material used in the insoles, EMG measurement during walking on flat ground, the target

population being individuals with pes planus, the muscles in which EMG activation was evaluated and the parameter evaluated in EMG analysis. For this reason, we consider it appropriate to evaluate each factor in itself.

Wulandari et al. [25] investigated the effect of shoes with insoles of different stiffness on EMG activation during walking in healthy subjects and compared 4 conditions: flexible, semi-flexible and rigid insoles with bare feet. The results showed that there were significant differences between the four walking conditions for several statistical parameters such as peak, peak time, peak duration, and onset of peak amplitude for the gastrocnemius medialis, tibialis anterior and vastus medialis muscles. In our study, there was no difference in %MIC between EMG activations of tibialis anterior, gastrocnemius medialis, peroneus longus and soleus muscle without and with insoles. Compared to Wulandari et al. [25], one reason for the difference in our analysis result may be that the population we studied was individuals with pes planus. Another reason may be that the reference value is the EMG %MIC value that we evaluated without insoles with the person's own shoes, not bare feet.

There are also studies examining the effect of insoles stiffness on EMG muscle activation in the population with pes planus. Huang et al. [29] compared the effect of different insoles on the EMG fatigue parameter in the rectus femoris muscle during downhill and uphill walking in pes planus and stated that the stiffness of the sole will increase not only the physical sensory input but also the fatigue of the lower extremity muscles. Our study differs from the study of Huang et al. [29] in terms of walking on flat ground, the muscles measured by EMG and the parameter (%MIC) examined in EMG.

Another factor that may affect the effectiveness of orthoses on EMG is whether they are prefabricated or customized. In our study, the effect of prefabricated insoles on EMG muscle activation was examined. Ahmad et al. [30] compared the EMG RMS and fatigue parameters of the tibialis anterior and peroneus longus muscles during gait by comparing the commercially available prefabricated insoles with custom-made insoles and reported that the custom-made insoles gave better results in terms of the parameters examined. In another study, in 10 rheumatoid arthritis patients with posterior tenosynovitis and pes planus, the effect of barefoot, shoe and customized insoles variables on muscle activation during the sole contact and midstance-push phase of gait was compared and it was found that the timing of peak amplitude of the soleus and gastrocnemius medialis muscle changed and the peak amplitude of the tibialis anterior muscle increased [31].

Murley et al. [33] compared EMG activation during different phases of gait between individuals with pes planus and individuals with normal arch of the foot without insoles, with prefabricated and customized insoles and found an increase in tibialis anterior muscle peak amplitude (19%) and a decrease in peroneus longus muscle activity (13%) in the group with pes planus during the contact phase of gait. During mid-stance-push, the group with pes planus exhibited increased activity in the tibialis posterior (26%) and decreased activity in the peroneus longus (14%) compared to those with normal feet. During the contact phase of gait, tibialis posterior EMG amplitude was shown to be significantly reduced with the prefabricated orthosis (19%) and the custom orthosis (12%) compared to the shoe-only condition. In contrast, during the mid stance-push phase), the peroneus longus EMG amplitude was significantly increased with the prefabricated orthosis (19% and 14% increase, respectively) compared to the shoe only and custom orthotic conditions ($p<.05$). Our study is similar to Murley et al. [33] in terms of including individuals with pes planus and evaluating tibialis anterior and peroneus longus muscle activation by dividing into gait phases. However, compared to Murley et al. [33], there was no control group. In addition to tibialis anterior and peroneus longus muscles, gastrocnemius medialis and soleus muscles were also included in EMG measurement. Gait was divided into 4 phases and mid-stance and push-off phases were evaluated as two separate phases. Comparisons between measurements were made between no insoles and insoles of different materials. All the insoles we used were prefabricated and it remains unclear how the degree of stiffness of individualized insoles will affect EMG muscle activation.

Another factor that may affect the research result is the duration of insoles use. Saeedi et al. [32] evaluated the effect of prefabricated modified UCBL orthosis on muscle activation of tibialis anterior, peroneus longus and gastrocnemius medialis muscles during gait after 1 month of use in 21 male individuals with asymptomatic pes planus and reported that the orthosis increased the muscle activity of peroneus longus compared to barefoot. In our study, the acute effect of insoles was evaluated. Therefore, the long-term effect of insoles on EMG in individuals with pes planus and its interpretation is unknown.

Another factor that may affect the study results is the transverse arch support height in the insoles. Since all silicone insoles with sufficient arch support in the market also have transverse arch support, the other two types of insoles were selected from those with transverse arch support. However, the transverse arch support height could not be standardized among different types of insoles used in the study due to their unavailability in the market. Therefore, it is not known how the transverse support height of the insoles used in individuals with pes planus affects muscle activation during walking.

Limitations

The small sample size due to the pandemic, using the same height of arch supports for each participant and the lack of simultaneous video recording during EMG measurements are the limitations of our study. Using synchronous camera recording systems during EMG measurements in different phases of gait in individuals with pes planus may provide clearer information in dividing the gait four phases (heel strike, mid-stance, push-off and swing) and analyzing each phase.

CONCLUSION

In our study, a large-scale comparison of lower extremity muscle activation measured in the heel strike, mid-stance, push-off and swing phases of gait in individuals with pes planus was made between insoles and without insoles and insoles made of different materials. In the literature, there are studies examining the effect of insoles on EMG muscle activation in individuals with pes planus, but our study is the only study examining the effect of the material on muscle activation in different phases of gait. The following results were obtained in our study;

1. In individuals with pes planus, rigid (steel) insoles decreased tibialis anterior muscle activation in the heel strike (0-10%) phase of gait compared to the swing phase (60-100%). The use of steel insoles should be discouraged because they reduce tibialis anterior muscle activation in the heel strike phase compared to the swing phase, and they distract muscle activation from the normal foot pattern during gait.

2. In individuals with pes planus, semirigid (polyform) insoles caused an increase in peroneus longus muscle activation in the mid-stance phase of gait (10%-40%) compared to the swing phase (60%-100%). The use of thermoplastic insoles may be recommended for individuals with pes planus because polyform insoles provide medial arch support by increasing peroneus longus muscle activation in the mid-stance phase compared to the swing phase.

Ethical Approval: *2021/73 Bolu Abant Izzet Baysal University Clinical Research Ethics Committee*

Conflict of Interest: *The authors have no conflicts of interest to declare.*

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Author Contribution: Concept: *TÇ,EE;* ***Design:*** *TÇ,EE;* ***Data collecting:*** *EE;* ***Statistical analysis:*** *TÇ,EE;* ***Literature review:*** *EE;* ***Writing:*** *TÇ,EE;* ***Critical review:*** *EE.*

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