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Journal of Nursology

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Unlocking the Potential of Technology in Nursing Skills Education: A Randomized Controlled Trial

Hemşirelik Becerileri Eğitiminde Teknolojinin Potansiyelinin Ortaya Çıkarılması: Randomize Kontrollü Bir Çalışma

ABSTRACT

Objective: This study aimed to determine the effect of illustrated checklists and web-access videos on nursing students' basic nursing knowledge levels and psychomotor skills.

Methods: This single-blind, randomized controlled trial was conducted with 205 first-year nursing students registered in a Fundamentals of Nursing course. The students were stratified by gender and randomly assigned to the experimental and control groups using simple randomization. All students participated in theoretical lectures, demonstrations, and laboratory practices. The Intervention Group's laboratory practices were supported by illustrated checklists and web-access skill videos.

Results: The intervention group's objective structured clinical exams and knowledge test scores were significantly higher than the control group's ($P < .05$). In total, 95.4% of the students stated that watching videos facilitated learning.

Conclusion: The study found that illustrated checklists and web-accessible skill videos improved students' knowledge and skills and that the skill videos facilitated learning, increased motivation, and enhanced clinical preparation. The widespread use of illustrated checklists and web-access skill videos in nursing skills education is suggested.

Keywords: Nursing education; nursing psychomotor skill; checklist; technology; web-based education

ÖZ

Amaç: Bu çalışma, resimli kontrol listeleri ve web erişimli videoların hemşirelik öğrencilerinin temel hemşirelik bilgi düzeyleri ve psikomotor becerileri üzerindeki etkisini belirlemeyi amaçladı.

Yöntemler: Bu tek kör, randomize kontrollü çalışma Hemşirelik Esasları dersine kayıtlı 205 birinci sınıf hemşirelik öğrencisi ile yürütüldü. Öğrenciler cinsiyete göre tabakalandırıldı ve basit randomizasyon kullanılarak deney ve kontrol gruplarına rastgele atandı. Tüm öğrenciler teorik derslere, demonstrasyonlara ve laboratuvar uygulamalarına katıldı. Müdahale grubunun laboratuvar uygulamaları resimli kontrol listeleri ve web erişimli beceri videoları ile desteklendi.

Bulgular: Müdahale grubunun objektif yapılandırılmış klinik sınavları ve bilgi testi puanları kontrol grubuna göre anlamlı derecede yüksekti ($P < .05$). Toplamda, öğrencilerin %95,4'ü video izlemenin öğrenmeyi kolaylaştırdığını belirtti.

Sonuç Çalışmada, resimli kontrol listeleri ve web erişimli beceri videolarının öğrencilerin bilgi ve becerini geliştirdiği ve beceri videolarının öğrenmeyi, motivasyonu ve klinik hazırlığı kolaylaştırdığı saptandı. Hemşirelik becerileri eğitiminde resimli kontrol listelerinin ve web erişimli beceri videolarının yaygın kullanımı önerilmektedir.

Anahtar Kelimeler: Hemşirelik eğitimi; hemşirelik psikomotor beceri; kontrol listesi; teknoloji; web tabanlı eğitim

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INTRODUCTION

Nursing is a holistic discipline intended to provide students with knowledge, attitudes, and skills in cognitive, affective, and psychomotor learning areas.¹ The psychomotor domain requires competence in nursing care-related psychomotor skill practices.¹⁻³ It is essential to have competent and effective nurses to provide patients with safe, evidence-based, and patient-centred care.⁴

Technology-supported teaching methods have become more common in nursing education since the 1990s, when traditional teaching methods dominated. The results of the integrative review by Gause et al. showed that technology in nursing education continues to be increasingly used in clinical and classroom teaching to complement learning.⁵ Silveira et al.'s⁶ integrative review reports that technology use makes teaching more dynamic and allows for active learning methods, breaking the moulds of traditional teaching, which is focused on demonstrating and repeating procedures.

In this context, student-centred educational approaches that are flexible in space and time, appealing to today's Z-generation students (born between the mid to late 1990s and early 2012s)⁷, and providing active learning experiences have gained importance.⁸ One of the main reasons for this is the change in the students' profile and learning styles. Therefore, the teaching methods should also be structured and formatted in a student-centred way to cater to the needs and learning styles of the next generation.⁹⁻¹¹ In addition to traditional teaching methods, technological developments offer alternatives for teaching nursing knowledge and skills.⁴

In nursing education, ensuring the active participation of the students is essential. Various technologies, including web-accessible skill videos and checklists, support nursing students' knowledge and skill development. With this technology, students can work in a flexible time frame and wherever they want until they come to class. At the same time, students can study the videos repeatedly according to their learning speed. With the advancement of these technologies, it becomes clear that learning is no longer limited to textbooks and traditional classrooms.¹²⁻¹⁴ Many studies in the literature show that technological methods such as skill videos, websites, and checklists contribute to developing students' skills. These technological methods have been widely used recently. For example, Chuang et al.'s¹² study (n = 87) found that the intervention group (IG) had higher knowledge and skill levels than the control group (CG), which lacked access to the application after watching a video on the urinary catheterization technique.

A website including skill videos and checklists for insertion of nasogastric tubes, bloodletting, and peripheral intravenous catheterization was created as part of the qualitative descriptive study by Barisone et al.¹³ The students could access these videos and the checklists before and during clinical practice. Students who participated in focus groups said that using checklists and videos in addition to laboratory exercises may lower the likelihood of making mistakes and that web-based learning enhances knowledge and abilities by linking theory and practice. A study by Luctkar-Flude et al.¹⁵ (n = 83) developed a respiratory distress patient scenario and learning outcomes assessment rubric. Before the simulation, the students received the prepared rubric. Ninety per cent of the students said that accessing the rubric before the simulation helped them better prepare for the application and understand what was expected of them. According to Stone et al.'s¹⁴ integrative review framework study, skill videos watched by nursing students via video podcasts improve learning and boost self-esteem and self-efficacy. In addition to the numerous positive contributions of technology to nursing education, it is essential to address the challenges that may impede educational activities. These challenges include hardware and software malfunctions, unreliable internet connectivity, concerns regarding the security of personal information, and disparities in access to technology among students. These issues can result in significant disruptions or limitations in the educational process. Effective technology integration in nursing curricula necessitates addressing these obstacles to ensure a seamless and secure learning environment for students.⁵

As reflected, skill checklists and videos used in studies were used only to develop a limited number of skills within the scope of the study. This study aimed to develop all basic nursing knowledge and skills taught in the scope of the Fundamentals of Nursing course. In this context, unlike the studies in the literature, illustrated checklists and web-access videos were used for all nursing skills within the scope of the Fundamentals of Nursing course. Additionally, this study evaluates the impact of technology use on the development of cognitive knowledge and psychomotor skills among students. These systems with various technologies must be easily accessible to students at any time and place. Unlike similar studies, this study allowed students to view the prepared videos anytime, anywhere, and as much as they wanted through the Internet. Thus, this approach could provide students with unforgettable experiences. In this context, this study is considered original and is anticipated to contribute substantially to the

nursing education literature.

AIM

This study aimed to determine the effect of illustrated checklists and web-access videos on nursing students' basic knowledge levels and psychomotor skills.

Thus, the following hypotheses were tested:

Hypothesis 1. Illustrated checklists and web-access videos are effective in increasing the basic knowledge levels of nursing students.

Hypothesis 2. Illustrated checklists and web-access videos are effective in improving the psychomotor skills of nursing students.

METHODS

Study Design

This study was a single-blind, randomized, controlled study. The students were unaware of the group allocations throughout the study. In addition, the researchers who collected data through observation during the OSCE did not know which group the students belonged to. However, the researchers who did not participate in data collection knew the group of students to ensure organisation.

Features and Place of The Study

This study was conducted in the 2018-2019 academic year as part of the Fundamentals of Nursing course in the Nursing Department of a public university's Faculty of Health Sciences.

This course is compulsory in the first-year curriculum in the fall (Theoretical: 3 hours; Practice: 3 hours) and spring (Theoretical: 4 hours; Practice: 12 hours). Infection control and vital signs topics are the subjects of the fall term. Besides, the subjects of the spring term include hygiene, hot-cold applications, movement requirements, administering medications, fluid requirements, respiratory, nutrition, urinary elimination, and bowel elimination. Lecturers explain the theoretical issues taught in this course in terms of the lecture and question-answer and discuss teaching methods. After the theoretical class, the faculty members demonstrated nursing skills related to the subject. Then, the students were divided into small groups in the laboratory and applied the process steps on manikins and simulators under the instructor's supervision. The students' psychomotor skills are assessed through laboratory applications, clinical practice in the hospital, and objective structured clinical exams (OSCE).

Participants

Of the 272 students enrolled in the Fundamentals of Nursing course, 210 students who met the inclusion criteria constituted the study sample. The sample size was determined using power analysis. To test a moderate effect

size ($d = 0.5$), it was calculated that at least 86 students should be included in each group. The margin of error for the IG was 5%, and the power value was 90%. A 20% increase in the sample size accounted for the expected loss.¹⁶ These students were stratified according to gender by simple randomization using the draw method and divided into intervention ($n=105$) and control ($n = 105$) groups. A total of two students with absenteeism, over 20%, were excluded from the IG during follow-up and three from the CG during analysis. The analyses were conducted with 103 students from the IG and 102 students from the CG.

Inclusion criteria

- To be enrolled in the course for the first time
- Voluntary participation in the study

Exclusion criteria

- Having completed any health discipline education before

Dismissing criteria

- Absenteeism of $20 \leq$ and above from the course
- Requesting to leave the study

Data Collection

The data was collected through the sociodemographic characteristics form (15 questions on students' age, gender, nursing profession choice, etc.), skill checklists on 11 main units, knowledge tests (KT), and student opinion form (24 statements including their views on the technology used in the course).

The students' knowledge levels were assessed separately in the fall and spring semesters. A KT consisting of 15 questions for the subjects in the fall semester and 37 questions for the subjects in the spring term was prepared. The KT consists of multiple-choice questions with five options. Each question was evaluated based on one point, and the total score was converted to a 100-point system. The questions were assessed by five experts in the field of Fundamentals of Nursing, and the necessary corrections were applied. A preliminary application of the questions was conducted with the students ($n = 240$) in the first grade in the previous academic year. The questions that the students did not understand finding them exceedingly wrong or easy, were rearranged.

The skill development levels of the students who had completed their learning related to basic nursing skills were assessed with OSCE, conducted separately in the fall and spring semesters by the researchers (EE, GE, ND, SA, CG). During the fall term, the students were given two stations related to vital signs minutes (Station 1 = 7 minutes) and infection control (Station 2 = 7 minutes). Likewise, OSCE, which consists of four stations related to the skills of fluid

requirement skills (Station 1 = 9 minutes), respiratory and administering medications (Station 2 = 9 minutes), urinary elimination (Station 3 = 9 minutes), bowel elimination and nutrition (Station 4 = 9 minutes), were applied to the students in the spring term. After completing the skill at one station, the student applied the skill at the other station with a ringing tone indicating the end of the station's set period. The students' skills with a minimum master's degree in the subject area were observed and assessed at each station by the instructors by marking them on skill control lists.

Application of the Study

The study was conducted in three stages: preparation, intervention, and evaluation.

Preparation

Publishing the Basic Nursing Skills Book: Researchers have developed evidence-based skill checklists based on the literature,¹⁷⁻¹⁹ encompassing 11 core subjects covered in the course.²⁰ The checklists were reviewed by three faculty members who were experts in their fields and finalized in line with the feedback. Professional photographs were taken to illustrate the execution of the critical steps and placed in the relevant process steps in the book. Thus, the book was finalized and published.

Shooting nursing skills videos: In line with the previously prepared skill checklists, 23 basic nursing skills were professionally filmed. A professional voice-over was performed to explain the steps of the process in the videos.

Creation of the website: The website (<https://www.hemsirelikbecerileri.net/tr>) was created, and educational videos were uploaded. The students in the IG could access videos on this website with their usernames and passwords. The website did not track detailed data on whether students watched the videos or their viewing patterns. However, log-in details proved that students accessed the platform during the intervention.

Intervention

Teaching basic nursing skills for the groups: Basic nursing skill training continued for one academic year, including the fall and spring semesters. Each skill was taught weekly by researchers who were experts on the subject within the scope of the course. All the students were taught a theoretical class on each skill, which was then demonstrated, and small-group laboratory studies were applied. The theoretical class on the course was taught simultaneously to students in groups by the researchers (ZB, NC). The content of each theoretical course lasted approximately four-course hours (50 minutes × 4 hours = 200 minutes).

All the students performed laboratory practice in groups of 15 and performed each skill on a mannequin under the instructor's (EE, GE, ND, SA, CG) supervision. Additionally, IG watched the videos of each skill in the laboratory and studied the process steps of the related skill from the skill checklists. The IG could also access videos on the website and watch them repeatedly at any time and place after the theoretical class and laboratory practices.

A CONSORT flow diagram, including the research's application steps, is shown in Figure 1.

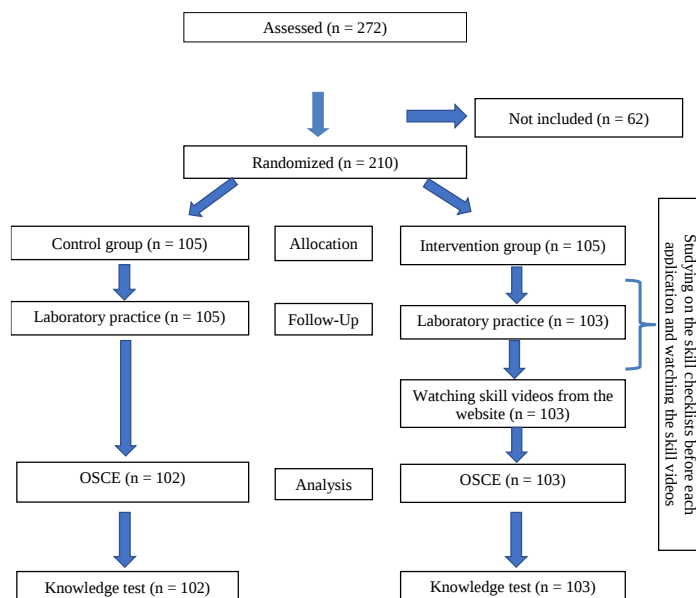


Figure 1. CONSORT diagram of this study

Data Analysis

Statistical analyses were performed using Statistical Package for Social Science (IBM SPSS 24 Corp., Armonk, NY, USA). Descriptive statistics methods such as number, percentile, mean, standard deviation, median, minimum, and maximum values were used to evaluate the obtained sociodemographic data. The Mann-Whitney U test and chi-square test were used to compare the introductory characteristics of the test and CGs in terms of similarity, and the Mann-Whitney U test was used to compare the average scores from the OSCE and end-of-term exams. Effect sizes were used in statistically significant hypothesis testing and power analysis. $P < .05$ value was accepted for the significance level of the statistical tests.

Ethical Considerations

Permission was obtained from the Gazi University Ethics Commission (15/06/2017-E.86926). The university's written approval and informed consent from students were received to collect data. After the study was completed,

nursing skill videos prepared within the scope of the study were shown to the students in the CG.

RESULTS

In the study, all the students' sociodemographic characteristics were similar in the groups ($P > .05$) (Table 1).

Table 1. Sociodemographic Characteristics (n = 205)

Characteristics	The IG (n = 103) n (%)	CG (n = 102) n (%)	Test/P X ² /P
Gender			
Female	85 (82.5)	81 (79.4)	.152
Male	18 (17.5)	21 (20.6)	.697
Willingness to choose the profession			
Voluntary choice	92 (89.3)	90 (88.2)	.001
Involuntary choice	11 (10.7)	12 (11.8)	.980
Being pleased to be a nursing student			
Satisfied	96 (93.2)	91 (89.2)	.581
Unsatisfied	7 (6.8)	11 (10.8)	.446
Daily computer usage time			
Never	62 (60.2)	67 (65.7)	
1 hour	31 (30.1)	24 (23.5)	1.127
1-5 hours	10 (9.7)	11 (10.8)	.569
Daily mobile phone usage time			
1 hour	8 (7.8)	4 (3.9)	1.691
1 hour	65 (63.1)	63 (61.8)	.194
1-5 hours	25 (24.3)	26 (25.5)	
5-10 hours	5 (4.9)	9 (8.8)	
Whenever I am awake			
Age			z/P
Mean $\pm$ SD	19.50 $\pm$ 0.80	19.49 $\pm$ 1.66	-1.647
Med-(Min, Max)	19.00 (18-23)	19.00 (18-29)	.099

IG; Intervention Group, CG; Control Group, X²; Chi Square, SD; Standard Deviation, z; Z score

Table 2 shows the KT scores of the groups. While there was no statistically significant difference between the KT score medians for the fall term of the groups ($P > .05$), there was a statistically significant difference between the spring term KT scores and their medians ($P < .05$). Accordingly, the spring term KT score medians were significantly higher than those in the CG. The effect size was 0.35 (Table 2).

Table 3 shows the OSCE score medians of the groups. There was no statistically significant difference between the infection control OSCE score medians among the groups ($P > .05$).

However, there was a statistically significant OSCE score difference between the groups: vital signs, administering medications, fluid requirement, nutrition, respiratory, urinary elimination, bowel elimination, and the average of all OSCE scores ($P < .05$). Accordingly, the medians of the average scores of all OSCE, except the infection control,

were significantly higher than those in the CG.

Table 2. The KT Scores of the Groups

KT score	Intervention group (n=103) Mean $\pm$ SD Med-(Min-Max)	Control group (n=102) Mean $\pm$ SD Med-(Min-Max)	z/P Effect size
Fall term	65.58 $\pm$ 12.15	62.7 $\pm$ 11.81	-1.725/
KT score	65.0-(35.0-95.0)	65.0-(35.0-85.0)	.084
			0.24
Spring term KT score	72.89 $\pm$ 9.86 74.4-(41.0-92.3)	69.53 $\pm$ 9.39 69.2-(51.3-89.7)	-2.705/ .007 0.35

KT; Knowledge Test, SD; Standard Deviation, Med; Median, Min; Minimum, Max; Maximum, z; Z score

Effect sizes were found between 0.37 and 0.75 in the skill test scores, with statistically significant differences between the groups (Table 3).

Additionally, 95.4% (N = 98) of IG students stated that watching videos facilitated the learning process, and 93.1% (N = 96) said the skill videos boosted their motivation to learn. According to 87.4% (N=90), the technology increased interest in the lesson, and 96.5% (N = 99) said that they made applying easier.

Table 3. The OSCE Scores of the Groups

OSCE scores	Intervention Group (n=103) Mean $\pm$ SD Med-(Min-Max)	Control Group (n=102) Mean $\pm$ SD Med-(Min-Max)	z/P Effect size
Infection control	86.94 $\pm$ 7.49 87.3-(56.4-98.2)	85.52 $\pm$ 7.02 86.4-(65.5-98.2)	-1.806/ .071 0.19
Vital signs	83.00 $\pm$ 9.96 85.8-(51.7-98.3)	79.5 $\pm$ 8.85 80.0-(54.2-95.0)	-3.282/ .001 0.37
Administering medications	86.21 $\pm$ 10.21 88.0-(42.0-100.0)	81.96 $\pm$ 11.33 84.0-(30.0-100.0)	-3.041/ .002 0.59
Fluid requirements	76.78 $\pm$ 13.02 80.0-(33.0-100.0)	72.06 $\pm$ 12.42 74.0-(33.0-95.0)	-2.876/ .004 0.37
Nutrition	88.35 $\pm$ 11.20 92.0-(46.0-100.0)	81.92 $\pm$ 15.52 86.0-(24.0-100.0)	-3.352/ .001 0.48
Respiratory	88.33 $\pm$ 9.13 90.0-(58.0-100.0)	82.76 $\pm$ 8.27 84.0-(52.0-100.0)	-4.900/ .000 0.64
Urinary elimination	81.60 $\pm$ 11.07 83.0-(41.0-98.0)	72.45 $\pm$ 13.16 76.0-(41.0-92.0)	-5.141/ .000 0.75
Bowel elimination	88.49 $\pm$ 11.50 90.0-(32.0-100.0)	82.43 $\pm$ 16.24 86.0-(8.0-100.0)	-3.090/ .002 0.43
Total score	84.96 $\pm$ 7.24 86.2-(60.6-97.4)	79.82 $\pm$ 6.90 81.4-(61.2-94.4)	-5.529/ .000 0.73

OSCE; Objective Structured Clinical Exams, Z; Z score, SD; Standard Deviation, Min; Minimum, Max; Maximum, Med; Median

DISCUSSION

Teaching basic theoretical knowledge and related skills is critical in nursing education. In our study, the KT score medians of the subjects related to administering medications, fluid requirement, respiration, nutrition, urinary elimination, and bowel elimination taught in the spring semester were significantly higher than those in the CG (Table 2). In the videos, the skills checklist was explained in detail. Due to this reason, it is believed that the students in the IG achieve higher scores on knowledge tests as they acquire theoretical knowledge of the skill by watching instructional videos. The skill teaching environment, which has become more visual by adding technological methods, may have increased students' curiosity and desire to access these skills' theoretical knowledge. In the study by Kobra et al.²¹ with midwifery and nursing students ($n = 84$), two teaching methods related to hand hygiene were compared. The video hand hygiene demonstration was given to the IG, and the usual theoretical lecture PowerPoint demonstration was given to the CG. The groups' knowledge levels were evaluated with multiple-choice questions before and after the initiatives. The students' knowledge levels in the IG were statistically significantly higher than before the intervention ($P < .05$). There was no statistically significant improvement in the knowledge level of the CG before and after the intervention ($P > .05$). In a study by Lee et al.²², a training video on urinary catheter application skills was prepared. While the CG students continued their usual curriculum, the IG had mobile access to the training video on the urinary catheter application skill. It was found that nursing students in the IG had higher knowledge scores on urinary catheterization. Natarajan et al.²³ found interactive video teaching was as effective as traditional face-to-face demonstration-based education on nursing students' oral drug administration knowledge level. As indicated by the research results, an educational environment enriched with visual and audio multimedia elements increases the students' level of subject-specific knowledge.

Many invasive and non-invasive skills are taught in nursing education, and students are expected to perform these skills independently. Our study determined that in all skills except infection control, the median OSCE scores in the IG were significantly higher than those of the CG. Additionally, it was observed that the students' mean scores in the taught skills progressively increased (Table 3). This increase in students' skill point averages is thought to result from using their previous learning outcomes in the following learning environment. The teaching skills should be simple to complex, easy to difficult, concrete to abstract, and

general to specific.²⁴⁻²⁵ While learning complex skills, students must use the relatively simple albeit essential skills they have known before. In addition, the use of videos that appeal to many sensory organs, prepared by expert educators during skill education, enables students to permanently learn complex and difficult-to-learn skills and increase their skill scores.

Kim et al. conducted a study on care practices for airway obstruction ($n = 73$).²⁶ A video of a smartphone app developed on the subject in the IG was uploaded to the students' phones. The demonstrations were organized for the CG. In the checklists created on the subject, the skill performance of the IG was statistically significantly higher than that of the CG ($P < .001$). Lee et al. found that nursing students studying the subject had higher skill scores by providing mobile access to the training video on urinary catheter application skills created by the researchers.²⁰ Barisone et al.¹³ determined that web-based learning effectively supported nursing students' clinical learning process. That study stated that web-based learning is effective in clinical learning by providing additional virtual visual support thanks to its ease of use and unlimited access. Using visually enriched learning tools, such as audio and video, and addressing multiple sensory organs in the students' skill education facilitates the teaching of complex skills. However, it is crucial that these learning tools be in the students' native language and that expert educators prepare them based on evidence.²⁷⁻²⁹

Study Limitations

The study has several limitations. Firstly, the scope of the study was limited to student nurses receiving education during the data collection period. Secondly, the opinions of the students in the intervention group were subjective.

As a result, it was found that the KT score medians of the IG students and OSCE scores (except one unit) were significantly higher than those in the CG. Furthermore, most students stated they wanted to work with skill videos as they facilitated their learning, increased their learning motivation, and eased their preparation for clinical practice. These results show that using technology significantly contributes to developing students' knowledge and skills toward basic nursing practices. Based on these results, it is recommended that various technologies (web-accessible videos and illustrated checklists, simulation, active learning methods, etc.) be expanded in nursing skills education. Additionally, it is recommended to plan studies with larger samples, using illustrated checklists and videos with the methodology developed in this study, to develop materials suitable for different learning styles and conduct multinational studies

with videos subtitled in English.

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The Effect of Mobile Application on Subcutaneous Anti-TNF Drug Administration in Ankylosing Spondylitis Patients: A Randomized Experimental Study

Ankilozan Spondilit Hastalarında Mobil Uygulamanın Subkütan Anti-TNF İlaç Uygulamasına Etkisi: Randomize DeneySEL Bir Çalışma

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ABSTRACT

Objective: This study was conducted to develop an Android mobile application for the subcutaneous (SC) administration of anti-TNF drugs in ankylosing spondylitis patients and to evaluate its effect on drug administration.

Methods: In the first stage of this randomized experimental study, a mobile application for SC anti-TNF drug therapy was developed. In the second stage, 32 patients who met the sampling criteria were randomized to mobil and booklet groups. Patients in both groups were evaluated using the Individual Identification Form, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), the Bath Ankylosing Spondylitis Functional Index (BASFI), the Ankylosing Spondylitis Quality of Life Scale (ASQoL) and Subcutaneous Anti-TNF Treatment Questionnaire once every 6 weeks for 6 months.

Results: In the first stage, the concordance coefficient of the five experts' opinions on the information provided in the mobile application was calculated as $W:0.272$, $P=.130$. For both patient groups, the mean scores of BASDAI, BASFI, and ASQoL were statistically significantly lower at the last evaluation than at the first. More patients in the education booklet group had their medication applied by someone else ($P=.011$).

Conclusion: The mobile application developed for SC anti-TNF therapy in AS patients is highly informative and reliable, and it facilitates the administration of SC anti-TNF drugs to patients.

Keywords: Ankylosing spondylitis, tumor necrosis factor inhibitors, subcutaneous injections, mobile applications, nursing

ÖZ

Amaç: Bu çalışma, ankilozan spondilit (AS) hastalarının subkütan (SC) anti-TNF ilaç uygulamasına yönelik bir Android mobil uygulama geliştirmek ve bu uygulamanın ilaç uygulamasına etkisini değerlendirmek amacıyla yapıldı.

Yöntemler: Bu deneySEL çalışmanın ilk aşamasında SC anti-TNF ilaç tedavisine yönelik mobil bir uygulama geliştirildi. İkinci aşamada örnekleme kriterlerini karşılayan 32 hasta mobil ve kitapçık gruplarına randomize edildi. Her iki gruptaki hastalar 6 ay boyunca her 6 haftada bir Bireysel Tanıtım Formu, Bath Ankilozan Spondilit Hastalık Aktivite İndeksi (BASDAI), Bath Ankilozan Spondilit Fonksiyonel İndeksi (BASFI), Ankilozan Spondilit Yaşam Kalitesi Anketi (ASQoL) ve Subkütan Anti-TNF Tedavi Anketi kullanılarak değerlendirildi.

Bulgular: İlk aşamada 5 uzmanın mobil uygulamada sunulan bilgilere ilişkin görüşlerinin uyum katsayısı $W:0,272$, $P=.130$ olarak hesaplandı. Her iki hasta grubunda da BASDAI, BASFI ve ASQoL ortalama puanları son değerlendirmede ilk değerlendirmeye göre istatistiksel olarak anlamlı derecede düşüktü. Eğitim kitapçığı grubunda ilacını başkasına yaptıran hasta sayısı daha fazlaydı ($P=.011$).

Sonuç: AS hastalarında SC anti-TNF tedavisi için geliştirilen mobil uygulamanın bilgi kalitesi ve güvenilirliği yüksek olup hastaların SC anti-TNF ilaçları uygulamasını kolaylaştırmıştır.

Anahtar Kelimeler: Ankilozan spondilit, Tümör nekroz faktörü inhibitörleri, subkütan enjeksiyonlar, mobil uygulamalar, hemşirelik

INTRODUCTION

Ankylosing spondylitis (AS) affects the spine, sacroiliac joints, and, rarely, the peripheral joints; it causes pain, stiffness, and progressive restriction in the spine.¹ The Assessment of the SpondyloArthritis International Society (ASAS) and the European League Against Rheumatism (EULAR) recommend using biological agents alongside the traditional pharmacological treatment of AS in individuals with high disease activity.² Among the biological agents, five different FDA-approved anti-tumor necrosis factors (TNFs) are used in treating AS.³ The entry of anti-TNF drugs into pharmacological treatment has changed the direction of disease management and has been effective in treatment.⁴ Besides being effective, the use of a foreign protein for the drugs can cause injection-site reactions, autoantibody production, autoimmune response development, and hypersensitivity reactions. Anti-TNF drugs pose a risk for the reactivation of tuberculosis in patients with latent tuberculosis disease and can lead to serious infections, malignancy, and hematological disorders.⁵ Patients should be especially careful about the possibility of infection and consult a physician in cases of fever, fatigue, or malaise. Most anti-TNF drugs (etanercept, adalimumab, certolizumab pegol, and golimumab) are administered as a subcutaneous (SC) injection, thus allowing patients to self-administer at home.⁶ The self-injection procedure helps patients increase their independence and accept treatment more easily, reducing the frequency of hospital visits and reducing costs.⁷ Although subcutaneous anti-TNF drugs are more preferred than intravenously administered ones due to their portability and time-saving,^{6,7} These drugs require extra patient education on self-SC drug administration, storage conditions, monitoring of infections, and other side effects.⁸ Furthermore, during SC injection treatment, patients may experience difficulties while administering the drug due to fear of needles, reduced manual dexterity, site pain, anxiety and skin reactions^{6,9}, embarrassment^{9,10}, difficulties while preparing the drug¹⁰, feeling bad after an injection⁹, patient lack of confidence, incorrect administration, and medication non-adherence.¹¹ For these reasons, informing patients about the treatment, reminding them of the treatment schedule, evaluating them at each stage of treatment, and monitoring the side effects that may develop are important for effective disease management. Nurses' continuous interaction with patients during the treatment process, which is described as "easy to talk," plays an important role in helping patients overcome problems with chronic conditions and the need to self-administer medication.¹² Regular follow-up of the health care team, a positive and supportive approach, and

comprehensive health education on ankylosing spondylitis and drug administration increase patient medication adherence and quality of life and reduce health service utilization.¹³

Today, with the increasing popularity of smartphones, there are many easily accessible mobile health applications.¹⁴ Studies in which mobile applications are developed for SC drug administration are limited. Domańska et al.¹⁵ have developed a mobile application that can only be used by patients with rheumatoid arthritis treated with certolizumab pegol SC injection. In a mobile health study for AS patients, it was seen that a mobile application was developed that provides medical information about the disease and includes exercise videos for patients with axial spondyloarthritis and psoriatic arthritis.¹⁶ In another study, a theory-based educational intervention was conducted via the social networking application WeChat on disease knowledge, self-efficacy, exercise adherence, and health outcomes in Chinese AS patients.¹⁷ This study aimed to develop a mobile application for the SC anti-TNF drug administration of AS patients on the Android platform and to evaluate its effect on drug administration.

AIM

This study was conducted to develop an Android mobile application for the SC administration of anti-TNF drugs in AS patients and to evaluate its effect on drug administration.

Research Hypotheses

H₀: The effects of the mobile application and the education booklet on SC anti-TNF drug administration of AS patients are no different.

H₁: Mobile application is more effective compared to the education booklet on regular SC anti-TNF drug administration of AS patients.

H₂: Mobile application is more effective compared to the education booklet on SC anti-TNF drug self-administration of AS patients.

METHODS

Study Design

This randomized experimental study methodology was carried out in two stages. The first stage involved developing a mobile application for the SC anti-TNF drug administration of AS patients on the Android platform, and the second stage evaluated the mobile application's effect on anti-TNF drug administration in AS patients. According to the CONSORT-2010 checklist, this study is reported and registered at www.clinicaltrials.gov (NCT04301128).

In the first stage of the study, the mobile application was developed in three phases: design, development, and implementation.

Phase 1. Design: In the design phase, the written material for the Android mobile application was created by the researchers in accordance with the literature. The written material was then combined with and supported by diagrams and images to reinforce learning. The written text was developed in line with the literature^{18,19}. It included information about the disease, the drug (effects of the drug, storage conditions), preparation and administration of the drug (administration site, cleaning of administration site, SC injection), and post-administration processes (closure of the administration site, waste management). The application also provided reminders about when to administer the drug, how to monitor side effects such as infection and signs of allergic reaction, how to give feedback from the monitoring via the mobile application, and daily care (oral care, infection control, food preparation and consumption, personal hygiene). There was also a management panel within the application where the researcher could monitor the feedback given by the patients. The researcher could log in to this panel with a username and password and monitor the patient's treatment and drug administration, their daily body temperatures and any infections or side effects noted, as well as send information and warning messages to patients about their disease and treatment. The written material was evaluated by a total of five experts, two of whom are doctors and three of whom are nurses, who work in this field and have publications in terms of information quality and information reliability, using the DISCERN Instrument measurement tool.

Phase 2. Development: In this phase, we worked with a software company to transfer the written material to the mobile application using Android programming. The prepared material was converted into a Turkish mobile application with Android programming. Organization, harmony, presentation, interaction, and navigation elements were considered when creating the mobile application. The mobile application has been prepared with an organizational structure that is as simple and easy to use as possible to appeal to all patients (Figure 1).

Phase 3. Implementation: The applicability of the developed mobile application was checked using 5 patients who were not included in the research sample. A problem was detected in the mobile application's feedback function in this preliminary research practice. After resolving this problem, the mobile application was ready for patients' use.



Figure 1. Shows a screenshot of mobile app home page

Study Setting and Sample

In the second study, the research universe consisted of patients prescribed SC anti-TNF drugs for AS at the Rheumatology Outpatient Clinic of Eskişehir Osmangazi University, Health, Practice and Research Hospital between December 2017 and December 2019. 32 patients who met the inclusion criteria were included in the sample. Patients were assigned to the groups using a simple randomization method. The patients were assigned to the groups by drawing lots (mobile group:18; booklet group:14) (Figure 2). Post-hoc power analysis was performed using the "Chi-square Goodness-of-fit test" in the G*Power 4 program, according to the answers given by the patients to the question "How often was your medication administered by someone else?" The power of the study was found to be 0.86 (effect size:0.59) with a significance level of 0.05 for type 1 error as a result of post-hoc power analysis with 32 patients.

Inclusion and exclusion criteria

The study's inclusion criteria were receiving SC anti-TNF drugs for the first or second time, being 18 years old or over, being Turkish literate, having and being able to use an Android phone, having internet access, being able to communicate, and volunteering to participate in the research. Those who had previously received more than

two SC anti-TNF drugs, whose anti-TNF drug treatment had been terminated, and who did not want to participate in the study were excluded from the research.

Data Collection

- The first evaluation (week 0) of the patients was performed using the Individual Identification Form, the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), the Bath Ankylosing Spondylitis Functional Index (BASFI), and the Ankylosing Spondylitis Quality of Life Scale (ASQoL) tools.
- Patients in both groups were orally informed about administering anti-TNF drugs. The researcher evaluated their body temperature as per their physician's request, and they received their first treatment. The patients were given a digital thermometer for further treatments and taught how to measure their body temperature.
- The mobile application was installed via Bluetooth technology on the Android phones of the patients in the mobile group. Usernames and passwords were created for the patients in this group to log in, and information about the drugs (drug name, frequency of administration) was recorded. The mobile application was introduced to the patients informed about receiving online data. Patients can access information about AS and anti-TNF drug administration and management anytime. The data entries saved in the mobile application by the patients were checked by the researcher using the patient monitoring panel. Patients who did not enter data were sent warning messages via the monitoring panel.
- Patients in the booklet group were given an education booklet, the written version of the mobile Android application. They were asked to refer to this booklet during their next treatment, measure and record their body temperature, and take medication if it was below 37.5 °C.
- Patients in both groups were evaluated using the BASDAI, BASFI, ASQoL, and the SC Anti-TNF Treatment Questionnaire once every six weeks for six months in accordance with the expert opinion of the rheumatologist.

Outcomes and Measurement

The primary outcomes of this study were patients' opinions of the SC Anti-TNF Drug Questionnaire.

The secondary outcomes of this study were patients' BASDAI, BASFI, and ASQoL scores. Data were collected using the Individual Identification Form, BASDAI, BASFI, ASQoL, Subcutaneous Anti-TNF- α Treatment Questionnaire, and DISCERN Instrument (Quality of Criteria for Consumer Health Information).

Individual Identification Form: The researchers developed this form, which consisted of 13 questions about the patient's diagnosis, age, gender, marital status, educational status, habits, and treatment plan.

BASDAI, BASFI, and ASQoL: Turkish version of BASDAI²⁰, BASFI²¹, and ASQoL²² were used. BASDAI consists of six questions about fatigue, spinal pain, joint swelling, joint tenderness, and morning stiffness, to evaluate disease activity in the past week.²⁰ BASFI consists of 10 questions: eight are about activities of daily living, and two are about coping with life. Each question is scored from 0 to 10 points.²¹ ASQoL consists of 18 questions with two options, "Yes" / "No," scored "1" and "0," respectively. Total scores range from 0 to 18, with a higher score indicating poor quality of life.²²

Subcutaneous Anti-TNF- α Treatment Questionnaire: The researchers created this to evaluate the treatment status of patients using an anti-TNF drug. A semi-structured interview form was created by the researchers, which included drug information, storage conditions, dose skipping/forgetting, patient injection practices, difficulties encountered during drug administration, and side effects.^{18,19} Semi-structured interview forms were filled out in 45-60 minutes through in-depth interviews with 10 patients not included in the sample. An item pool containing 30 questions was created. 5 experts evaluated the appropriateness of each statement in the created item pool. After the experts' opinions, the necessary revisions were made, and a 25-item questionnaire was created. The opinions of five experts were obtained to evaluate the questions, and the content validity index was calculated. The questionnaire was applied and tested with 5 patients with the same characteristics as the sample group. These 5 patients were not included in the study. The experts' answers to the Subcutaneous Anti-TNF Treatment Questionnaire were evaluated using the content validity formula. The questionnaire's CVI (Content Validity Index) was calculated as 1. The CVI value was greater than 0.80, indicating that the questionnaire was statistically valid.²³

DISCERN Instrument: This instrument evaluates the quality and reliability of training materials providing information in the health field and consists of 16 questions. The first eight questions (1-8) measure the reliability of the information included in the material; the next seven questions (9-15) measure the quality of the information in the material. The last question (16) evaluates the material in general.²⁴

Ethical considerations

Ethics committee approval was obtained from Eskişehir Osmangazi University Clinical Research Ethics Committee

before the study (date: 27.09.2017, number: 80558721/261). Written permission was obtained from the relevant institution where the study was conducted. All patients were informed about the study, and their written informed consent was obtained. The study was carried out in accordance with the Declaration of Helsinki.

Statistical Analysis

The data were analyzed in the IBM SPSS Statistics V 21.0 (IBM SPSS Corp., Armonk, NY, USA) package program. The Shapiro-Wilk test was used to test the suitability of quantitative variables to the normal distribution. Quantitative variables with normal distribution were presented as mean±standard deviation and mean±standard error; those that did not fit normal distribution were presented as median and quartiles (Q1-Q3). The intergroup distribution of quantitative variables that showed normal distribution was compared using the t-test, and the distribution of those that did not show normal distribution was compared using the Mann-Whitney U test. Distributions of repeated measurements according to the groups were evaluated using a two-factor analysis of variance with a one-factor repeated measure. Summary values of qualitative variables were shown using frequency and percentage. The correlation between qualitative variables was tested using Pearson's Exact Chi-squared test and Fisher's Exact Chi-squared test. Expert opinions on the content of the mobile Android application were evaluated using Kendall's W to determine the degree of concordance.

RESULTS

The study included 34 patients who met the sampling criteria out of 90 patients who received SC anti-TNF treatment. Of the patients included in the sample and both groups, one was diagnosed with cancer, and the other had a skin reaction, and her treatment was terminated. Therefore, the study was completed with 32 patients (Figure 2).

DISCERN Instrument and Expert Opinions on the mobile application

When the written material for the mobile application was evaluated using the DISCERN instrument, the score obtained from the first 15 questions was 65.4±11.32 out of 75; the general score was 5.0±0 out of 5. The concordance coefficient of the five experts' opinions on the quality and reliability of the information provided in the mobile application was calculated as $W:0.272$, $P=.130$ (Supplement Table 1). The quality and reliability of the information in this mobile application developed for anti-TNF drug administration of AS patients were high, according to the experts, and this showed that patients could safely use the application.

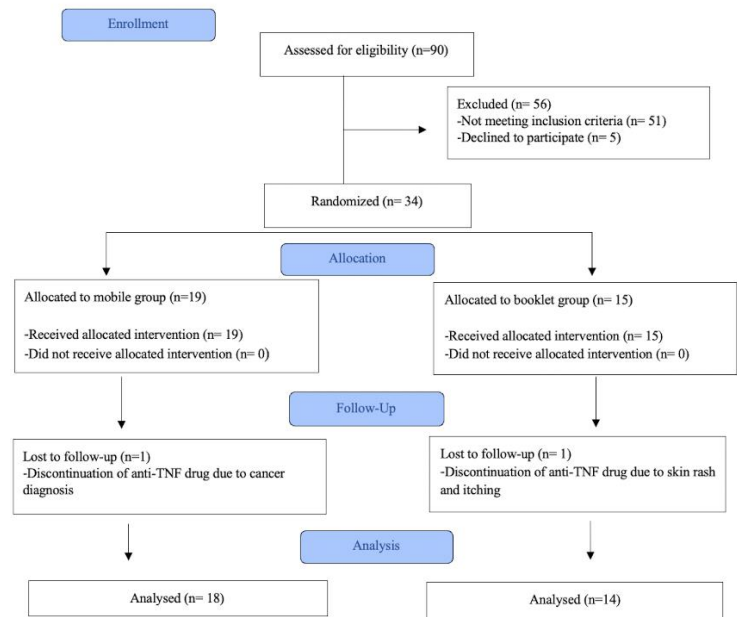


Figure 2. CONSORT flow chart of the research

Patients' sociodemographic, disease, and treatment characteristics

When the sociodemographic, disease, and treatment characteristics of the patients were compared, no statistical difference was found between the patients in both groups in terms of age, gender, marital status, educational status, employment status, drug prescribed, and presence of chronic disease, and the groups were similar ($P>.05$). The mean age of the patients in the mobile and booklet groups was 37.38 ± 11.77 years and 41.78 ± 16.03 years, respectively. The majority of the patients in both groups were male (75%), married (65%), and high school graduates (50%) who worked full-time (62.5%). The mean disease duration was 8.6 ± 5.7 years in the mobile group and 12.9 ± 12.6 years in the booklet group. Patients in the mobile group had received AS treatment for seven years, and patients in the booklet group had received treatment for three and a half years (Table 1).

Patients' subcutaneous anti-TNF drug administrations

Table 2 shows the patients' opinions of the SC Anti-TNF Drug Questionnaire at weeks six and 24, respectively. According to the SC Anti-TNF Drug Questionnaire, more patients in the booklet group had received help from someone else to administer the drug at weeks six and 24 (week 6: $P=.003$; week 24: $P=.011$) (Table 3). At week 24, four patients in the booklet group had not administered their drugs in the previous six weeks, thinking that their disease was under control ($P=.028$).

Table 1. Distribution of socio-demographic, disease and treatment characteristics of patients

Characteristics		Mobil group Mean±SD		Booklet group Mean±SD		t	P	
Age (year)		37.38±11.77		41.78±16.03		-0.895	.378	
Duration of disease (year)		8.6±5.7		12.9±12.6		-1.282	.210	
Duration of treatment (year)		Median (Q1-Q3) 7.0(3.75-10.5)		Median (Q1-Q3) 3.5(0.9-17.0)		Test* 119.0	P .808	
		n		n		Total n	χ ²	P
Gender	Female	5	27.8	3	21.4	8	25.0	— ^a 1.000
	Male	13	72.2	11	78.6	24	75.0	
Marital status	Married	13	72.2	8	57.1	21	65.6	2.846 ^b .319
	Single	5	27.8	6	42.8	11	34.4	
Education level	Primary school	3	16.7	4	28.6	7	21.8	5.648 ^b .215
	Secondary school	2	11.1	0	0.0	2	6.3	
	High-school	11	61.1	5	35.7	16	50.0	
	Undergraduate	2	11.1	4	28.6	6	18.8	
	Postgraduate	0	0.0	1	7.1	1	3.1	
Employment status	Full time	12	66.7	8	57.1	20	62.5	1.413 ^b .706
	Part time	0	0.0	1	7.1	1	3.1	
	Unemployed	6	33.3	5	35.7	11	34.4	
Previous treatment	NSAIDs	18	100.0	14	100.0	30	93.8	— ^a .492
	Anti-Rheumatic Drugs	18	100.0	11	78.5	29	90.6	
	Immune regulatory drugs	8	44.4	7	50.0	15	46.8	
Prescribed Anti-TNF Drug	Etanercept (pen)	3	16.7	4	28.5	7	21.9	8.441 ^b .068
	Adalimumab (injector)	0	0.0	2	14.3	2	6.3	
	Adalimumab (pen)	1	5.5	3	21.4	4	12.5	
	Sertolizumab pegol (injector)	4	22.2	5	35.7	9	28.1	
	Golimumab (pen)	10	55.5	0	0.0	10	31.3	
Chronic disease**	Yes	3	17.7	5	35.7	8	25.0	— ^a .252
	No	15	83.3	9	64.3	24	75.0	

*Mann-Whitney U Test, **Diabetes mellitus, Hypertension, Coronary Artery Disease, Asthma, SD; Standard Deviation, t; Independent Sample t-test, ^aFisher's Exact Chi-Squared; ^bPearson Exact Chi-Squared, χ²; Chi-Squared Test

There was no regarding problems experienced during drug administration ($P>.05$). In general, patients were easily able to continue the SC anti-TNF drug treatment and were satisfied with the treatment at week six ($P>.05$) (Supplement Table 2); however, at week 24, the patients in the mobile group were more easily able to continue their treatment ($P=.027$) and were more satisfied with the treatment compared to the booklet group ($P=.002$, Table 2).

BASDAI, BASFI, and ASQoL score comparison

The mean BASDAI, BASFI, and ASQoL scores of the patients in both groups decreased by a statistically significant level ($P<.001$) in each evaluation from week 0 to week 24. The changes in the mean BASDAI and BASFI scores over time differed by groups ($P=.025$ and $P=.037$, respectively), and this difference resulted from the mean scores at week six ($P=.007$ and $P<.001$, respectively). When the mean BASDAI, BASFI, and ASQoL scores of the patients were examined, the mean scores of all three scales were found to be statistically significantly lower in the mobile group than in

the booklet group ($P<.05$) (Table 3).

DISCUSSION

In our study, the DISCERN Instrument was used to evaluate the information quality and reliability of the mobile application. This measurement tool evaluates the relevance and quality of the information given about treatment.²⁴ DISCERN Instrument have been used previously to evaluate web-based health education and written materials online.^{25,26} Maximum 75 points from 15 questions in the measurement tool; A maximum of 5 points is taken from the last question, which is evaluated separately from these, and the high scores indicate that the quality and reliability of the material is high.²⁴ Our written material for the mobile application score obtained from the first 15 questions was 65.4±11.32 out of 75; The general score was 5.0±0 out of 5. According to this result, the mobile application we developed for anti-TNF drug administration in AS patients has high information quality and reliability and can be used safely by patients.

Table 2. Comparison of some responses of patients regarding subcutaneous anti-TNF drug administration in the 24th week evaluation

Questions			Mobil group n	Booklet group n	Total	X ²	P
Anti-TNF drugs should be stored according to the cold chain rule		Yes	17	13	30	— ^a	1.000
		No	1	1	2		
Drug administration frequency		Once a week	3	4	7	0.766 ^b	.813
		Once every two weeks	5	4	9		
		Once a month	10	6	16		
Did you inject your drug with a prefilled syringe or use an auto-injector (pen)?		Prefilled syringe	4	7	11	— ^a	.142
		Auto-injector	14	7	21		
How often was your drug administered by someone else?		I always administered it myself	14	5	19	7.999 ^b	.01
		Administered several times by someone else	4	5	9		
		It was always administered by someone else	0	4	4		
Have you ever forgotten to take your drug or not taken on time in the last 6 weeks?		Yes	4	6	10	— ^a	.267
		No	14	8	22		
What factors were effective in forgetting to take your drug?	Memory problems	Yes	2	2	4	— ^a	1.000
		No	16	12	28		
	Busyness	Yes	2	3	5	— ^a	1.000
		No	16	11	27		
	Needle phobia	Yes	0	1	1	— ^a	1.000
		No	18	13	31		
	Drug side effect	Yes	0	2	2	— ^a	.183
		No	18	12	30		
	Anxiety	Yes	1	0	1	— ^a	1.000
		No	17	14	31		
Have you ever had to postpone your drug by consulting your doctor?		I never postponed	16	11	27	2.803 ^b	.423
		Postponed due to flu infection	2	1	3		
		Postponed due to fatigue	0	1	1		
		Other*	0	1	1		
Have you ever preferred not to take your drug, considering that your disease is under control?		Yes	0	4	4	— ^a	.028
		No	18	10	28		
Have you ever experienced bleeding in the injection area while taking your drug?		Never	10	5	15	1.524 ^b	.508
		Sometimes	7	7	14		
		Mostly	1	2	3		
Have you ever experienced pain, stinging, burning, or pain in the injection area while taking your drug?		Never	9	9	18	4.571 ^b	.161
		Sometimes	9	3	12		
		Mostly	0	1	1		
		Always	0	1	1		
Have you ever experienced itching or irritation in the injection area while taking your drug?		Never	18	11	29	— ^a	.073
		Sometimes	0	3	3		
Have you ever felt frustrated or anxious while taking your drug?		Never	16	10	26	— ^a	.365
		Sometimes	2	4	6		
Have you ever experienced swelling, stiffness, or lump in the injection area after taking your drug?		Never	17	13	30	— ^a	1.000
		Sometimes	1	1	2		
Have you ever experienced any abnormal redness or rash in the injection area after taking your drug?		Never	18	12	30	— ^a	.183
		Sometimes	0	2	2		
Have you ever experienced bruising in the injection area after taking your drug?		Never	13	9	22	— ^a	.712
		Sometimes	5	5	10		
			Median (Q1-Q3)	Median (Q1-Q3)		Test**	P
Overall difficulty level in continuing SC anti-TNF drug treatment			0(0-2)	2(1-4)		70.00	.027
Satisfaction level with anti-TNF drug treatment in the last 6 weeks			10(9-10)	8(5-10)		51.00	.002

*Prescription problem, ** Mann-Whitney U Test, X²; Chi-squared, ^aFisher's Exact Ki-kare; ^bPearson Exact Ki-kare

Table 3. Comparison of the distribution of patients' BASDAI, BASFI and ASQoL scales score

Scales		Mobil group		Booklet group		Time	<i>P</i> [*]	
		Mean	Standard error	Mean	Standard error		Group	Time X group
BASDAI	0th week	5.7	0.36	5.8	0.41	<.001	.040	.025 ^a
	6th week	1.8	0.41	3.8	0.46			
	12th week	1.7	0.30	2.5	0.34			
	18th week	1.6	0.34	2.1	0.39			
	24th week	1.2	0.19	1.5	0.21			
	^a 6th week (<i>P</i> =.003)							
BASFI	0th week	4.9	0.60	4.9	0.68	<.001	.033	.037 ^b
	6th week	1.0	0.34	3.1	0.39			
	12th week	0.6	0.22	1.2	0.24			
	18th week	0.5	0.22	0.6	0.25			
	24th week	0.2	0.10	0.5	0.12			
	^b 6th week (<i>P</i> <.001)							
ASQoL	0th week	10.7	1.02	9.7	1.16	<.001	.037 ^c	.076
	6th week	1.5	0.87	4.6	0.98			
	12th week	0.05	0.38	1.8	0.43			
	18th week	0.5	0.44	1.7	0.5			
	24th week	0.06	0.21	1.0	0.24			
	^c ASQoL score mean	2.5±0.38		3.8±0.43				

BASDAI; Bath Ankylosing Spondylitis Disease Activity Index, BASFI; Bath Ankylosing Spondylitis Functional Index, ASQoL; Ankylosing Spondylitis Quality of Life Scale; *Two-way repeated measures ANOVA for one factor, ^a, ^bStatistical significance of the mean score differences of scales at the 6th week, ^cStatistical significance of the mean scores differences of ASQoL in between groups

In the study in which internet-based information for individuals with Raynaud phenomenon and patients with systemic sclerosis were evaluated with DISCERN Instrument, the general score for both diseases was determined to be 1.0 (1.0-5.0), contrary to the score of our mobile application material.²⁵ In another study, it was observed that the DISCERN Instrument scores of web-based training developed for patients diagnosed with lung cancer were similar to the results of our study.²⁶

In our study, fewer patients in both groups forgot or missed their medication in the 6th week compared to the 24th week (Supplement Table 2 and Table 2). This may be because patients feel hope and excitement about a new treatment and adhere to their treatment program. This may also be associated with the fact that the researcher applied the treatment to both groups at the beginning of the study and gave training on the topic to the patients. However, in the evaluation's 24th week, four patients in the mobile application group had forgotten to take their drugs or had missed taking them five times. In comparison, six booklet group patients had forgotten or missed taking them 12 times. Patients in the booklet group stated that they did not administer their drugs because they forgot or were too busy, that they had a phobia of needles, and that there were side effects from the injection. In contrast, patients in the mobile application group stated that they did not administer their drugs because they forgot, were busy, had side effects from the injection, or had a phobia of needles. It has been stated that patients can skip drug doses in

SC treatment due to fear, pains, and aches,^{6,9} difficulty in preparing the injection¹⁰, feeling bad after the injection⁹, embarrassment^{9,10}, patient lack of confidence, and incorrect administration.¹¹ For these reasons, it is recommended that nurses consider these issues when training patients who self-administered their SC drug and include these points in the training.

At the 24th week evaluation, significantly more patients in the booklet group had not administered their drugs in the previous six weeks, thinking that their disease was under control (*P*=.028). Nurse-led interventions that include patient training, counseling, motivational interview-based medication adherence therapy, and reminders to take drugs affect the use of drugs regularly, health outcomes, functionality, hospitalization, and quality of life positively.²⁷ Telehealth support interventions are recommended to improve medication adherence, reduce health expenses and healthcare utilization, and improve self-care and health outcomes.²⁸ Özkaraman et al.²⁹ found that training provided by the nurse and telephone follow-ups were effective in adhering to the treatment of patients who had a rheumatological disease and who used an SC anti-TNF drug. Mobile group patients in our study receive reminder messages and have 24-hour access to notifications about side effects, information about the disease, and guides and relevant diagrams about administering SC drugs, which may be effective for them in administering their drugs more regularly. Furthermore, Barelló et al.³⁰ stated that a nurse-led, telephone-based patient support program improved perceived self-care skills, emotional coping for

the future, the unpredictability of the course of the disease, and general attitudes toward the injection itself, involving pain tolerance of multiple sclerosis patients receiving interferon-alpha therapy. In line with these results, it is recommended that nurses provide AS patients with information about their medications (effects of the drug, side effects, storage conditions, waste removal) and how to prepare and administer them and that they evaluate and consult with patients intermittently to improve drug administration easily and improve the health outcomes of those using SC anti-TNF drugs.

Today, the number of mobile applications available has increased alongside smartphones. However, there is only a limited number of mobile applications developed for AS patients with information about the disease,^{16,17} medication, exercise, daily life management, how to assess disease activity function, and reminders to take their medication¹⁷ and it is noteworthy that there has been no prior study examining SC anti-TNF drug administration and management among AS patients. Domanska et al.¹⁵ stated that the mobile application they developed for rheumatoid arthritis patients using certolizumab pegol, which supports them throughout their disease, helps patients better manage their treatment and disease. Similarly, Song et al.¹⁷ showed that the HBM-based educational intervention through mobile application improved patient disease knowledge and self-efficacy. In our study, the rate of self-administration was determined to be higher among the patients in the mobile group and lower in the booklet group. This may be due to the feedback given to the patients through the mobile application for solutions to the problems encountered while administering SC anti-TNF drugs.

In the 24th week of the evaluation of our study, the patients in the mobile group could more easily continue their treatment. They were more satisfied with the treatment than the booklet group. This result can be explained as being due to the patients receiving reminder messages and having 24-hour access to notifications about side effects, information about the disease, and guides and relevant diagrams about administering SC drugs. In addition, the number of patients who administered drugs with an auto-injector was higher in the mobile group. Roszkiewicz et al.³¹ reported that patients administered subcutaneous injection with an auto-injector device more easily than with a prefilled syringe showed a high degree of satisfaction experiencing the self-injection with auto-injector and had less pain and fewer problems when using an auto-injector. It is stated that drugs in the form of autoinjectors are more valuable for rheumatoid arthritis patients to improve their injection experience by reducing their fear and anxiety and

overcoming difficulties arising from dexterity problems.⁷ Ghil et al.³² explained in their study that patients with rheumatoid arthritis prefer adalimumab, an autoinjector, over a prefilled syringe. Likewise, while more than half of the patients in the mobile group used golimumab, none of the patients in the booklet group used golimumab in this study. Like other self-administered TNF inhibitors, Golimumab is administered monthly rather than weekly or biweekly. It is thought that the fact that golimumab has a monthly dosing schedule affects the fact that patients using this drug make the injection more easily and have a higher rate of treatment adherence. Therefore, to eliminate this factor, it is recommended that the sample group be divided according to the use of auto-injectors in subsequent studies. In addition, the healthcare team needs to consider the patient's preference when deciding on SC anti-TNF drug therapy, as the injection type facilitates adherence to treatment, which will lead to positive health outcomes and an increase in the patient's quality of life.

Anti-TNF drugs are an effective treatment option for AS patients and are used to reduce symptoms, slow down the radiological progression, and improve physical function. Decreased BASDAI and BASFI scores in AS patients indicate a remission in disease activity and improved physical function. Regularly monitoring AS patients using an anti-TNF is important in managing AS.³³ Initially, the patients in our study had high disease activity and moderate physical function. Similar to the literature, patients' BASDAI and BASFI scores had decreased significantly at the six-month follow-up.³⁴ This decrease was higher in the patients in the mobile group than in the booklet group ($P < .005$). Within the scope of the study, while the patients in the booklet group were informed once at the beginning of the treatment about the disease, anti-TNF treatment, healthy lifestyle behaviors, and situations to be paid attention to verbally and written; this information was presented constantly with the mobile device in the mobile group. Therefore, the mobile application informs patients about anti-TNF treatment, healthy lifestyle behaviors, and important points in daily care, thus ensuring that patients' motivation is high. It is predicted that this may effectively decrease the disease activity in patients.

Structural disorders in the spine and their symptoms lead to difficulties with daily living activities and a significant decrease in the quality of life of AS patients. Disease activity and functioning are among the strongest determinants of quality of life. Quality of life decreases as disease activity and functional loss increase.³⁴ Youssef and Rafey et al.³⁵ reported a significant decrease in mean ASQoL scores of AS patients six and 12 months after starting anti-TNF drug treatment. Likewise, in our study, the mean ASQoL scores

of patients in both groups had decreased at the end of the sixth month using anti-TNF drugs. Moreover, in our study, the mean ASQoL score was generally higher in the booklet group than in the mobile group ($P=.037$). This shows that the quality of life of the patients in the mobile group was higher than that of the patients in the booklet group. This can be explained by the fact that the decrease in disease activity and greater improvement in functional capacity positively affected patients' quality of life in the mobile group.

Strengths and Limitations of the study

The strengths of this study are that it is the first mobile application for SC anti-TNF drug administration in AS patients, that AS patients have a training material where they can access quality and reliable information about drug administration remotely, and that the healthcare team can follow them up during the treatment process. Despite that, this study has a limitation. Since the budget for the development of the mobile application was limited, only those whose smartphones ran on Android, the most popular operating system in Turkey, were included in the study. Smartphone users with the IOS operating system could thus not be included.

This study determined that the mobile application developed for SC anti-TNF therapy in AS patients has high information quality and reliability and facilitates the administration of SC anti-TNF drugs. For this reason, it is recommended that written and visual materials support the mobile application to facilitate the application of SC anti-TNF to patients who will self-administer SC anti-TNF at home.

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Hakem Değerlendirmesi: Dış bağımsız.

Yazar Katkıları: Fikir- FU, AÖ, CK; Tasarım- FU, AÖ, CK; Denetleme- AÖ, CK; Kaynaklar- FU, AÖ, CK; Veri Toplanması ve/veya İşlemesi FU; Analiz ve/veya Yorum- FU, AÖ; Literatür Taraması- FU, AÖ; Yazıyı Yazan- FU, AÖ; Eleştirel İnceleme- FU, AÖ, CK

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FU, AÖ, CK;

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Supplement Table 1. Distribution of mean scores of the information quality and reliability of the mobile training material

Discern Measurement Tool Question Items							Mean $\pm$ SD
1	Is its objective clear?						4.8 $\pm$ 0.44
2	Are the objectives achievable?						4.8 $\pm$ 0.44
3	Is it relevant to the subject?						4.8 $\pm$ 0.44
4	Are the resources stated clearly?						5.0 $\pm$ 0
5	Is the date of the reported or used information stated clearly?						4.8 $\pm$ 0.44
6	Is it impartial and consistent?						4.8 $\pm$ 0.44
7	Does it provide details on additional information or supportive resources?						4.0 $\pm$ 1.73
8	Are uncertain aspects mentioned?						2.6 $\pm$ 2.19
9	Does it describe how each treatment is administered?						5.0 $\pm$ 0
10	Does it describe the benefits of each treatment?						4.2 $\pm$ 0.83
11	Does it describe the risks of each treatment?						4.2 $\pm$ 0.83
12	Does it describe what will happen in the absence of treatment?						4.0 $\pm$ 1.73
13	Does it describe how treatment options affect the quality of life?						4.2 $\pm$ 1.78
14	Has the possibility of the presence of more than one treatment option been explained?						4.2 $\pm$ 1.78
15	Does it provide support for the patient in making decisions?						4.0 $\pm$ 1.73
16	General evaluation						5.0 $\pm$ 0
		n	Mean $\pm$ SD	Minimum	Maximum	Kendall's W	P
	Information quality	5	35.6 $\pm$ 4.03	31	40	0. 272	0.130
	Information reliability	5	29.8 $\pm$ 8.43	15	35		
	Total	5	65.4 $\pm$ 11.32	47	74		

SD; Standart deviation

Supplement Table 2. Comparison of some responses of patients regarding subcutaneous anti-TNF drug administration in the 6th week evaluation

Questionnaire Questions			Mobil application group	Booklet group	Total	χ ²	P
			n	n			
Anti-TNF drugs should be stored according to the cold chain rule	Yes		18	13	31	— ^a	.437
	No		0	1	1		
Drug administration frequency	Once a week		3	4	7	0.766 ^b	.813
	Once every two weeks		5	4	9		
	Once a month		10	6	16		
Did you inject your drug with a prefilled syringe or use an auto-injector (pen)?	Prefilled syringe		4	7	11	— ^a	.142
	Auto-injector		14	7	21		
How often was your drug administered by someone else?	I always administered it myself		15	4	19	11.041 ^b	.003
	Administered several times by someone else		3	6	9		
	It was always administered by someone else		0	4	4		
Have you ever forgotten to take your drug or not taken on time in the last 6 weeks?	Yes		2	4	6	— ^a	.365
	No		16	10	26		
What factors were effective in forgetting to take your drug?	Memory problems	Yes	2	2	4	— ^a	1.000
		No	16	12	28		
	Busyness	Yes	0	1	1	— ^a	.437
		No	18	13	31		
	Needle phobia	Yes	0	2	2	— ^a	.183
		No	18	12	30		
Have you ever had to postpone your drug by consulting your doctor?	I never postponed		16	12	28	1.427 ^b	.762
	Postponed due to flu infection		2	1	3		
	Other*		0	1	1		
Have you ever preferred not to take your drug considering that your disease is under control?	Yes		0	2	2	— ^a	.183
	No		18	12	30		
Have you ever experienced bleeding in the injection area while taking your drug?	Never		9	6	15	0.730 ^b	.768
	Sometimes		8	6	14		
	Mostly		1	2	3		
Have you ever experienced pain, stinging, burning or pain in the injection area while taking your drug?	Never		8	7	15	3.285 ^b	.285
	Sometimes		10	5	15		
	Always		0	2	2		
Have you ever experienced itching or irritation in the injection area while taking your drug?	Never		18	13	31	— ^a	.437
	Sometimes		0	1	1		
Have you ever felt frustrated or anxious while taking your drug?	Never		17	9	26	— ^a	.064
	Sometimes		1	5	6		
Have you ever experienced swelling, stiffness or lump in the injection area after taking your drug?	Never		17	14	31	— ^a	1.000
	Sometimes		1	0	1		
Have you ever experienced any abnormal redness or rash in the injection area after taking your drug?	Never		18	12	30	— ^a	.183
	Sometimes		0	2	2		
Have you ever experienced bruising in the injection area after taking your drug?	Never		11	9	20	— ^a	1.000
	Sometimes		7	5	12		
			Median (Q1-Q3)	Median (Q1-Q3)	Test**	P	
Overall difficulty level in continuing subcutaneous anti-TNF drug treatment			1.5(0-3)	4(2-6)	80.00	.074	
Satisfaction level with anti-TNF drug treatment in the last 6 weeks			9(8-10)	8.5(4-10)	98.5	.280	

^aFisher's Exact Ki-kare. ^bPearson Exact Ki-kare. *Prescription Problems. **Mann-Whitney Test

^aFisher's Exact Ki-kare, ^bPearson Exact Ki-kare, *Prescription Problems, **Mann-Whitney Test

Turkish Validity and Reliability of the Nursing Students' Rights Awareness Scale in Clinical Practice

Hemşirelik Öğrencilerinin Klinik Uygulamadaki Haklarının Farkındalığı Ölçeği Türkçe Geçerlik ve Güvenirlik Çalışması

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ABSTRACT

Objective: To adapt the Nursing Students' Rights Awareness Scale into Turkish and test its validity and reliability.

Methods: This was a methodological study performed with 296 nursing students between 11 April and 10 June 2022 in the capital city of Turkey. Expert opinions were taken for the language and content validity of the scale. Exploratory and Confirmatory Factor Analyses were used to test construct validity. Cronbach's alpha coefficient was used for internal reliability. Test-retest was conducted using the Intra-Class Correlation and Spearman's rank correlation.

Results: The Content Validity Index was 0.87. The scale, which originally had three factors, was formed in a single-factor structure in the current study, and the factor loads ranged from 0.563 to 0.871. The variance explained for the single-factor structure consisting of 14 items was 63.7%. The Cronbach's alpha was 0.95. The Intra-Class Correlation value was 0.95 (95%CI= 0.938-0.956, $P<.001$) and the Spearman's rank correlation coefficient was 0.70.

Conclusion: The Turkish version of the Nursing Students' Rights Awareness Scale is a valid and reliable instrument.

Keywords: Clinical practice nursing research, human rights, nursing student, validity and reliability

ÖZ

Amaç: Bu çalışmanın amacı Hemşirelik Öğrencilerinin Klinik Uygulamadaki Haklarının Farkındalığı Ölçeğinin Türkçe geçerlik ve güvenirliğini test etmektir.

Yöntemler: Bu metodolojik çalışma, 11 Nisan-10 Haziran 2022 tarihleri arasında Türkiye'nin başkentinde, 296 hemşirelik öğrencisi ile yapılmıştır. Ölçeğin dil ve kapsam geçerliğini değerlendirmek için uzman görüşleri alınmıştır. Yapı geçerliğini değerlendirmek için açımlayıcı ve doğrulayıcı faktör analizleri yapılmıştır. İç güvenirlik, Cronbach alfa katsayısı ile değerlendirilmiştir. Test-tekrar test güvenirliği, grup içi korelasyon ve Spearman sıra farkları korelasyon katsayısı ile test edilmiştir.

Bulgular: Ölçeğin kapsam geçerlik indeksi 0,87 olarak bulunmuştur. Orijinalinde üç alt boyutu olan ölçek, Türkçe uyarlamasında tek alt boyutta toplanmış ve faktör yükleri 0,563-0,871 arasında değişmiştir. On dört maddeden oluşan tek faktörlü yapı için açıklanan varyans %63,7 idi. Ölçeğin grup içi korelasyon değeri 0,95 (95% Güven aralığı: 0,938-0,956, $P<.001$) ve Spearman sıra farkları korelasyon katsayısı 0,70 idi.

Sonuç: Hemşirelik Öğrencilerinin Klinik Uygulamadaki Haklarının Farkındalığı Ölçeğinin Türkçe versiyonu geçerli ve güvenilir bir ölçme aracıdır.

Anahtar Kelimeler: Klinik uygulama hemşirelik çalışması, insan hakları, hemşirelik öğrencisi, geçerlik ve güvenirlik

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INTRODUCTION

Nursing education aims to gain the knowledge, skills, behaviors, and attitudes necessary for fulfilling the duties of the nursing profession. For this reason, nursing education is a professional process that includes the components of professional values, well-structured, theoretical, and clinical knowledge and skills, which will contribute to the development of students in many aspects.^{1,2}

Clinical practice is an essential part of nursing education in developing personal, professional, and clinical skills.^{3,4} Although it is also described as putting theoretical knowledge into practice, clinical practice contains various dynamics within itself. These deficiencies may be related to the clinical environment and healthcare personnel. These may include limited clinical teaching space, lack of clinical practice procedures, inadequate collaboration with clinical staff, inconsistencies between curriculum objectives and content, lack of prerequisites before clinical practice, lack of appropriate opportunities for learning, etc. In addition, regarding the teaching staff; their small numbers and different clinical evaluation criteria of the teaching staff may be included. Another important factor may be student-related factors such as students' motivation and perceptions of clinical practice.^{5,6} In a study conducted in our country, students' emotions during clinical practice are affected psychologically, academically, physically, and socially. All these effects affect students' attitudes toward clinical practice.⁷ In a study conducted with nursing students, it was determined that 49.8% of the students experienced difficulties with nurses (37.5%), hospitals (27.0%), and theoretical education (13.5%) during clinical practice and believed that these difficulties could be partially resolved (46.6%).⁸

Nursing students also experience many exposures, as well as the advantages and aspects of clinical practice that need to be developed. These exposures have led to the emergence of important rights for nursing students such as protection from infections, protection from clinical accidents, and awareness of their rights. In addition to these rights, it is inevitable that students should practice in an environment where they are not neglected, exposed to physical and psychological violence, and where the importance of human rights is known.^{9,10} It is seen that there are legal regulations at the international level that prevent nursing students from harming patients in the clinic.¹¹ In our country (Official Gazette Date: 08.03.2010 Official Gazette Number: 27515) there are articles in the Nursing Regulations that require nurses to contribute to

the education of students.¹² Although nursing students have the same basic human rights as all humans in clinical practice, university nursing departments have them practice by their clinical practice guidelines.

There are many studies in the literature on the difficulties experienced by nursing students in clinical practice.¹³⁻¹⁵ The use of a valid and reliable measurement tool in studies is limited. For this reason, it is important to use the Nursing Students' Rights Awareness Scale developed by Park and Choi⁶ in different cultures. In our country, studies on the rights of nursing students and awareness of their rights are limited. Considering that especially professional compulsory courses are carried out with clinical practice, it becomes important to gain an assessment tool to evaluate the awareness of nursing students' rights in the clinical area.

AIM

The aim of this study was to conduct a Turkish validity and reliability study of the Nursing Students' Rights Awareness Scale in Clinical Practice.

Research questions/hypothesis

- Is the Turkish adaptation of the Nursing Students' Rights Awareness Scale in Clinical Practice a valid measurement tool?
- Is the Turkish adaptation of the Nursing Students' Rights Awareness Scale in Clinical Practice a reliable measurement tool?

METHODS

Study Design and Participants

The study is a methodological study conducted to determine the validity and reliability of the Nursing Students' Rights Awareness Scale adapted into Turkish. The study included 296 nursing students in the capital city of Turkey. The sample size is expected to be 5-10 times the number of items.¹⁶ In this direction, the minimum value of participants to be reached for the validity and reliability study of the "Nursing Students' Rights Awareness Scale in Clinical Practice" consisting of 14 items was determined as 140 and completed with 296 students. The inclusion criteria were; being educated in the second, third, and fourth years, having done the clinical practice of at least one course specific to the nursing profession, and participating voluntarily in the study. Accordingly, 86.8% of the students were females, the mean age was 21.31±1.59, and 36.1% were third-year students. Approximately 63% of students live in student dormitories. More than half of the students (71.3%) stated their perceived income as medium (Table 1).

Table 1. Descriptive Characteristics of Nursing Students (n=296)

Descriptive characteristics	n (%)
Age, Mean±SD	21.31±1.59
Gender	
Female	257 (86.8)
Male	39 (13.2)
Academic class	
Second year	99 (33.4)
Third year	107 (36.1)
Fourth year	90 (30.4)
Place of residence	
With family	83 (28.0)
In dormitory	186 (62.8)
Other	27 (9.2)
Perceived income	
Good	48 (16.2)
Moderate	211 (71.3)
Poor	37 (12.5)
Total days of clinical practice- Mean±SD	32.97±19.72
Perceived satisfaction level regarding nursing education	
Good	113 (38.2)
Moderate	168 (56.8)
Poor	15 (5.1)
Perceived satisfaction level regarding clinical practice	
Good	95 (32.1)
Moderate	170 (57.4)
Poor	31 (10.5)
Knowledge of one's rights in clinical practice	
Yes	144 (48.6)
No	41 (13.9)
Partially	111 (37.5)
Status of receiving information regarding rights in clinical practice	
Yes	196 (66.2)
No	100 (33.8)

SD; Standard deviation

Data Collection

The Participant Information Form and Nursing Students' Rights Awareness Scale were used in the study. The language and content validity of the scale were evaluated. Students who agreed to participate in the study were invited to a classroom, given data collection tools, and waited until they were finished filling out the questionnaires. The time to fill out the questionnaires was 10-15 minutes. Data were collected between 11 April and 10 June 2022. Test-retest was used to evaluate the consistency of the scale. Data collection tools were filled in individually by the students.

Instruments

The Participant Information Form: The form was developed by researchers in line with the literature.^{6,7,17} There were 11

questions about students' age, gender, academic class, place of residence, perceived income, clinical training duration, perceived satisfaction level from nursing education, perceived satisfaction level from clinical practice, knowing the rights they have in clinical practice, giving information about the rights in the pre-clinical term, the rights that students want to have in clinical practice.

Nursing Students' Rights Awareness Scale in Clinical Practice: It was developed by Park and Choi⁶ to assess nursing students' awareness of their rights in clinical practice. The original scale consists of three factors with 14 items. Items are scored between 1 (strongly disagree) and 5 (strongly agree). The scale has no cut-off value. As the score increases, the awareness of nursing students also increases. While the Cronbach's alpha reliability coefficient of the scale was 0.92, it was determined as 0.92, 0.83, and 0.82 for three factors, respectively.⁶

Data Analysis

Expert opinions were taken for the language and content validity of the scale. Davis technique¹⁸ was used for content validity. In the Davis technique, each item in the scale was evaluated in a four-point Likert type as (a) "very appropriate", (b) "appropriate but needs minor changes", (c) "needs major changes", and (d) "not appropriate".¹⁸ The scale was sent to a total of 11 experts. The experts were academicians working in the Department of Nursing. Five of the experts were professors, three were associate professors, and three were assistant professors. The Content Validity Index (CVI) and Content Validity Ratio (CVR) were used to get opinions from the experts. Exploratory Factor Analysis (EFA) and Confirmatory Factor Analysis (CFA) were tested for construct validity. EFA and CFA can be performed in scale adaptation studies.¹⁹ For data analysis, Statistical Package for the Social Sciences (SPSS) 21.0 version and LISREL 8.81 package programs were used.

The suitability of the data for exploratory factor analysis was evaluated with Kaiser-Meyer Olkin (KMO) and Bartlett Sphericity tests. The factor structure and factor loads of the scale were determined by using principal component analysis. Chi-Square Goodness (χ^2/df), Comparative Fit Index (CFI), Goodness of Fit Index (GFI), Root Mean Square Error of Approximation (RMSEA), Adjusted Goodness of Fit Index (AGFI), Standardized Root Mean Square Error (SRMR), and Normed Fit Index (NFI) values were checked. Cronbach's Alpha internal consistency analysis, item-total score correlations, and intra-class correlation were used to test the reliability of the scale. In addition, descriptive statistics such as number, percentage, mean, and standard

deviation were used in the study. The statistical significance level was taken as 0.05.

Ethical Considerations

The author was contacted through e-mail for the adaptation of the original scale to Turkish. Ethical approval (Date: 20.04.2022 Number: E.342513 Number: 2022-494) from Gazi University Ethics Committee and institutional permissions required for the study were taken for conducting the study. In addition, the students were informed about the aim of the study, and their informed consent was obtained. The students were given the message that the study was for scientific purposes only, no identity information of the students was needed, and their education would not be interrupted if they did not want to participate in the study. The study was conducted within the framework of the Declaration of Helsinki.

RESULTS

Students' Knowledge of Nursing Education

The mean of clinical training duration was 32.97 ± 19.72 days. More than half of the students rated their overall satisfaction with nursing education (56.8%) and clinical practice (57.4%) as moderate. Approximately 49% stated

that they knew about their right to clinical practice, and 66.2% stated that they were informed about their rights in clinical practice (Table 1). Also, the rights that students ($n=144$) want to have in clinical practice were listed as follows:

Being able to participate more actively in clinical practice and be supported to develop their skills (25%), Being able to practice individually, to be informed about clinical practices and expectations during clinical practice (5.6%), Seeing more clinical areas (3.5%), Seeing a fair, respectful and tolerant attitude from the team (28.5%), Being able to be evaluated objectively (2.1%), Being able to dress comfortably (2.8%), Being able to rest at appropriate intervals (8.3%), Being able to choose a patient, hospital and/or clinical area (6.25%), Refusal to perform duties unrelated to his profession (4.9%), Being able to complain (2.1%), Receiving salary, transportation and meal support (18.1%), Being able to express one's opinion freely (3.5%), Being able to study with instructors sufficiently (2.1%), Being able to give feedback about clinical practice (4.2%), Asking questions and getting answers (1.4%) and Maintaining personal security (2.8%) (Table 2).

Table 2. The Rights Students Want in Clinical Practice (n=144)

The rights that students want to have while doing clinical practice	n (%)*
Seeing a fair, respectful and tolerant attitude from the team	41 (28.5)
Being able to participate more actively in clinical practice and be supported to develop their skills	36 (25)
Receiving salary, transportation and meal support	26 (18.1)
Being able to rest at appropriate intervals	12 (8.3)
Being able to choose a patient, hospital and/or clinical area	9 (6.25)
Being able to practice individually, to be informed about clinical practices and expectations during clinical practice	8 (5.6)
Refusal to perform duties unrelated to his profession	7 (4.9)
Being able to give feedback about clinical practice	6 (4.2)
Seeing more clinical areas	5 (3.5)
Being able to express one's opinion freely	5 (3.5)
Being able to dress comfortably	4 (2.8)
Maintaining personal security	4 (2.8)
Being able to be evaluated objectively	3 (2.1)
Being able to complain	3 (2.1)
Being able to study with instructors sufficiently	3 (2.1)
Asking questions and getting answers	2 (1.4)

*Students gave more than one answer.

Validity

In order to ensure language validity, the original scale was sent to three lecturers who knew English and Turkish well, and they were asked to translate the scale into Turkish. After the translations received by the researchers were combined and a consensus was reached on the scale items, the scale items were translated back into English by a linguist who knew both languages at the native-language

level. An expert who was fluent in both languages was consulted for the translated version of the scale into English and the original version in English. In line with the suggestions received, the items were reviewed and minor changes were made to the relevant items. The opinions of 11 experts were taken for the content validity of the scale. The content validity index was found to be 0.87. The CVR of the items ranged from 0.82 to 1.00 (Table 3).

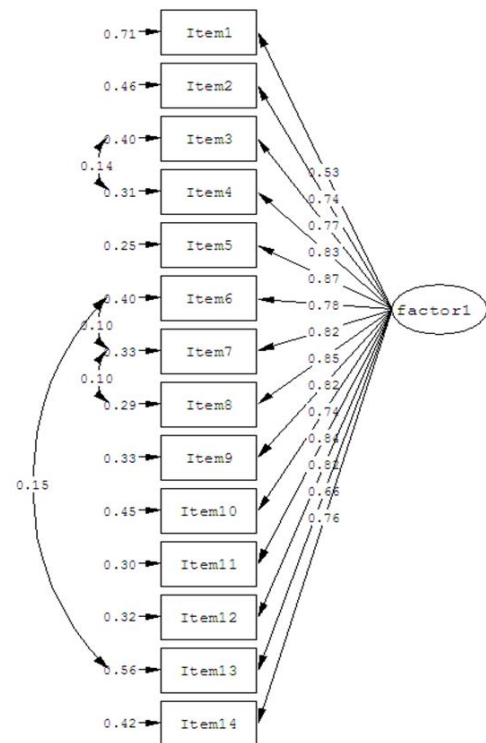
Table 3. Exploratory Factor Analysis (n=296)

Items		Communality	Factor 1	CVR
Item5	The university must have a system to respond systematically to the clinical training institution by representing the students in case of incidents and accidents that occur during the clinical training period, and to advocate for the students.	0.759	0.871	0.82
Item8	The clinical instructor must provide attention and support in guiding the students during clinical training.	0.745	0.863	0.91
Item4	The clinical instructor must pay attention to solving the students' suggestions or requests.	0.728	0.853	0.91
Item7	I have the right to be free from verbal, physical, and sexual assault.	0.724	0.851	0.91
Item11	I have the rights to receive a systematic orientation from a unit manager at the beginning of the clinical training.	0.702	0.838	0.82
Item9	I have the rights to ask questions to the nurse during clinical training and hear the answers.	0.683	0.826	0.82
Item12	I have the rights to be addressed by a title that shows respect to the students (e.g. A student nurse).	0.681	0.825	0.82
Item6	I have the rights to receive information about infection status of patients in advance.	0.663	0.814	0.91
Item3	Universities must have a system implemented for students to report any disadvantages or injustices experienced immediately.	0.637	0.798	0.82
Item14	I have the right to have the mealtime guaranteed.	0.619	0.787	1.00
Item2	I have the right to be treated respectfully.	0.589	0.768	0.82
Item10	I have the rights to learn according to the standardized clinical training manual.	0.577	0.760	0.82
Item13	I have the rights to not perform tasks that are not directly relevant to the clinical training.	0.493	0.702	0.91
Item1	I have the right to receive information in advance on the response instructions in case of an incident or an accident.	0.317	0.563	0.91
Eigenvalue			8.917	
Explained total variance			63.7%	
CVR; Content Validity Ratio				

The KMO value was 0.95, the Bartlett sphericity test value was found to be 3420,235 ($P<.001$) and showed that the data matrix and sample size were excellent in terms of factor analysis. Factor analysis was performed using the principal components method. A single-factor structure with an Eigenvalue above 1.0 and factor loads above 0.30 emerged. Accordingly, no item was removed from the data matrix as a result of exploratory factor analysis. The factor loads of the items varied between 0.563-0.871. The variance explained for the single-factor structure consisting of 14 items was 63.7%. As a result of the analysis, the common variance value explained by each item varied between 0.317-0.759 (Table3).

The suitability of the single-factor structure formed was evaluated by CFA. In this direction, a theoretical model was created and tested based on EFA. As a result of the analysis, modifications were made between items three and four, items six and seven, items seven and eight, and items six and 13, taking into account the correction indices (Figure 1). Fit indices of the resulting model; $\chi^2/df= 3.25$, CFI=0.98, GFI=0.90, RMSEA=0.08, AGFI=0.85, SRMR=0.036, NFI=0.98. After confirmatory factor analysis of the items, the standardized factor loads were between 0.53-0.87, and the regression coefficients were between 0.29-0.75.

Considering the Critical Ratio (CR) values, the values of items were statistically significant ($P<.001$) and ranged

**Figure 1. Confirmatory Factor Analysis**

Reliability

The Cronbach's alpha was 0.95. Test-retest analysis was conducted with 99 students. Test-retest reliability was evaluated using Intra-Class Correlation (ICC). Accordingly,

the ICC value of the 14-item scale with a single factor was found to be 0.95 (95%CI= 0.938-0.956, $P<.001$), and Spearman's rank correlation coefficient was 0.70 ($P<.001$) (Table 4).

Table 4. Reliability Analysis (n=296)

Items	Mean	SD	Item- Total correlation	Cronbach's alpha	Test-retest reliability ICC	95% CI
Factor 1				0.95	0.95	0.938-0.956*
Item 1	4.39	0.76	0.52			
Item 2	4.73	0.65	0.73			
Item 3	4.76	0.57	0.76			
Item 4	4.77	0.56	0.83			
Item 5	4.74	0.55	0.84			
Item 6	4.75	0.55	0.78			
Item 7	4.86	0.47	0.81			
Item 8	4.80	0.51	0.83			
Item 9	4.77	0.56	0.79			
Item 10	4.68	0.64	0.72			
Item 11	4.70	0.61	0.81			
Item 12	4.76	0.58	0.79			
Item 13	4.69	0.64	0.65			
Item 14	4.77	0.57	0.74			

* $P<.001$, SD; Standard Deviation

DISCUSSION

The transition between student and professional nurse can be facilitated through clinical experience. Students will get to experience what it's like in the profession and see if nursing aligns with their interests before committing to the clinical setting. Therefore, clinical practice should be seen as an integral part of nursing education. In clinical practice, which is indispensable for nursing education, situations that force students to struggle may arise.^{20,21} In our study, students want to be supported in the clinical environment, know their rights in the clinical environment, and feel like part of the team. In different studies, it is seen that these expectations coincide with the difficulties experienced by students in clinical practice.⁵⁻⁸ Students need to know their rights in order to benefit from clinical practices effectively and to adopt the clinic. There is no validity and reliability study of the scale in other languages. The results were discussed accordingly.

Validity is defined as the degree to which an instrument can accurately measure what it aims to measure without confusing it with any other characteristics.²² Typically, to ensure the validity of a scale, experts are frequently consulted in the evaluation of content validity. The scale items are evaluated by the experts in the relevant field.²³ The Turkish version of items was evaluated by 11 experts in this study. A CVI is expected to be at least 0.80.²⁴ In the current study, the CVI values were between 0.82-1.00. It shows that the scale items represent the population that

the research addresses.

Factor analysis was used to determine construct validity. The KMO coefficient and Bartlett sphericity test are used to determine the adequacy of the sample size.²⁵ A KMO coefficient should be more than 0.60.^{26,27} In this study, the KMO value was 0.95, Bartlett sphericity test value was 3420,235 ($P<.001$). The sample size was sufficient for exploratory factor analyses. The CFA was tested to assess the goodness of fit indices. In the current study, the standardized factor loads were 0.53-0.87. The factor loads were in the desired range. In the current study, the fit indices of the model were also; $\chi^2/df= 3.25$, CFI=0.98, GFI=0.90, RMSEA=0.08, AGFI=0.85, SRMR=0.036, NFI=0.98. The acceptable values of fit indices should be as follows: $3 < \chi^2/d < 5$; $0.90 \leq CFI \leq 0.95$; $0.90 \leq GFI \leq 0.95$; $0.05 < RMSEA < 0.08$, $0.90 \leq AGFI \leq 0.90$; $0.05 \leq SRMR \leq 0.10$ and $0.90 \leq NFI \leq 0.95$.^{28,29} When the normal value ranges of the fit indices are examined, it is seen that the values are acceptable.

Reliability indicates the capacity of the measuring instrument to evaluate all aspects of the variable. A scale's reliability is generally evaluated with time constancy and internal consistency criteria.^{30,31} The scale's internal consistency with Cronbach's alpha, should be above 0.70 to be acceptable.³² The Cronbach's alpha for the original scale was 0.92 and 0.95 in this study. A nother reliability test is the examination of the test-retest results of the scale. The scale was administered to 99 students using the test-retest

technique at 2-week intervals. The ICC values can yield values between 0 and 1. In our study, the ICC value was 0.95 (95%CI= 0.938-0.956, $P<.001$) and the Spearman's rho correlation coefficient was 0.70. These data showed that the scale is a consistent measurement tool against time.³³ Studies have shown that nursing students have difficulties in clinical practice. It is thought that using this scale is important in terms of increasing the awareness of nursing students through national and international studies.

Limitations

This study has some possible limitations. The first of these is that the research sample consists of students studying at a university. In addition, the fact that a specific measurement tool was not found to determine the scale's concurrent validity can be considered another limitation of the study.

This study was conducted to evaluate whether the scale is a valid and reliable tool that can be used in Türkiye. The scale originally consisted of three sub-dimensions with 14 items. As a result of analyses in this study, it has been determined that the scale can be used with a single factor. In addition, it is thought that validity and reliability studies can be conducted with different and larger numbers of students.

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Hakem Değerlendirmesi: Dış bağımsız.

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Peer-review: Externally peer-reviewed.

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The Effect of a Foot Bath on Sleep Quality in the Elderly: A Single-Blind Randomized Controlled Trial

Ayak Banyosunun Yaşlılarda Uyku Kalitesi Üzerine Etkisi: Tek Kör Randomize Kontrollü Bir Çalışma

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ABSTRACT

Objective: This study was conducted as a single-blind, randomized controlled parallel-group study with 50 elderly individuals to investigate the effect of foot bath on sleep quality.

Methods: The data were collected using the “Elderly Information Form” and the “Pittsburgh Sleep Quality Index (PSQI)” between 1 May 2022-1 July 2022 at a State Hospital in Gümüşhane province. The elderly in the foot bath group were given a foot bath with 41-42°C water for 20 minutes 50 minutes before normal sleep hours. No application was made to the control group except for the administration of data collection tools. The data were analyzed with Chi-square, Friedman, Wilcoxon Sign, and Mann-Whitney U tests.

Results: It was determined that at least one of the total PSQI measurements and median scores of all subcomponents obtained from the elderly in the foot bath group differed depending on time ($P<.05$). However, it was found that there was no statistically significant difference in the sleep latency (B2), sleep duration (B3), habitual sleep efficiency (B4) and sleep disturbance (B5) component measurements obtained from the elderly in the control group depending on time ($P>.05$). Again, All PSQI subcomponents and total PSQI scores, except for the subcomponent “Habitual Sleep Efficiency (C4)”, decreased throughout the application in the elderly in the foot bath group.

Conclusion: As a result, a foot bath improved sleep quality in the elderly. In line with the findings from this study, it is recommended to compare the foot bath with multiple experimental groups for a longer period of time.

Keywords: Elderly, sleep, foot, complementary therapies

ÖZ

Amaç: Bu çalışma, ayak banyosunun uyku kalitesine etkisini araştırmak amacıyla 50 yaşlı birey ile tek kör, randomize kontrollü paralel grupta bir çalışma olarak yürütüldü.

Yöntemler: Veriler “Yaşlı Bilgi Formu” ve “Pittsburgh Uyku Kalitesi İndeksi (PUKİ)” kullanılarak 1 Mayıs 2022 - 1 Temmuz 2022 tarihleri arasında Gümüşhane ili bir Devlet Hastanesinde toplandı. Ayak banyosu grubundaki yaşlılara normal uyku saatinden 50 dakika önce 41-42°C su ile 20 dakika ayak banyosu yapıldı. Kontrol grubuna veri toplama araçlarının uygulanması dışında herhangi bir uygulama yapılmadı. Veriler Ki-kare, Friedman, Wilcoxon İşareti ve Mann-Whitney U testleri ile analiz edildi.

Bulgular: Ayak banyosu grubundaki yaşlılardan elde edilen toplam PSQI ölçümlerinden ve tüm alt bileşenlerin medyan puanlarının en az birinin zamana bağlı olarak farklılık gösterdiği belirlendi ($P<.05$). Ancak kontrol grubundaki yaşlılardan elde edilen uyku latensi (B2), uyku süresi (B3), alışılmış uyku etkinliği (B4) ve uyku bozukluğu (B5) bileşen ölçümlerinde zamana bağlı olarak istatistiksel olarak anlamlı bir fark olmadığı bulundu ($P>.05$). Ayrıca, ayak banyosu grubundaki yaşlılarda uygulama boyunca “Alışkanlık Uyku Verimliliği (C4)” alt bileşeni dışındaki tüm PUKİ alt bileşenleri ve toplam PUKİ puanları azaldı.

Sonuç: Sonuç olarak ayak banyosunun yaşlılarda uyku kalitesini arttırdığı görüldü. Bu çalışmadan elde edilen bulgular doğrultusunda, ayak banyosunun çoklu deney grupları ile daha uzun süre karşılaştırılması önerilmektedir.

Anahtar Kelimeler: Yaşlı, uyku, ayak, tamamlayıcı tedaviler

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INTRODUCTION

Sleep consists of psychological, physiological, and social dimensions and has an extremely significant function in meeting basic human needs. Sleep affects everyone's daily life and quality of life.¹⁻³ One of the concepts that have been emphasized and gained importance recently is "*sleep quality*". Sleep quality is defined as "an individual's feeling ready and energetic for a new day after waking up". It is thought that sleep quality also has quantitative aspects such as falling asleep, sleep duration, number of awakenings at night, and subjective aspects such as restfulness or depth of sleep.^{4,5}

The population of elderly individuals is increasing day by day worldwide. In the changing age pyramid, the rate of elderly population was 9.7 % (8245124 people) (over 65 years of age) in 2021 and is estimated to be 11.0 % in 2025, 12.9 % in 2030, 16.3 % in 2040, 22.6 % in 2060, and 25.6% in 2080.^{6,7} With increasing age, changes occur in normal sleep patterns, complaints of insomnia increase, and satisfaction with sleep quality decreases.⁸ According to a literature review, sleep problems rank third among the reasons for visiting a doctor in the elderly, after digestive system problems and headache symptoms.⁶ The inability to fall asleep, waking up early in the morning, waking up frequently at night, and sleeping during the day are among the most common sleep-related problems in the elderly.⁹

Sleep problems in the elderly can cause serious problems but are also preventable. In this sense, all health personnel, especially nurses, should apply comprehensive nursing care to minimize sleep problems and improve sleep quality in the elderly. Pharmacological treatment is generally employed in the elimination of sleep problems. However, pharmacological treatment is inadequate in eliminating sleep problems, so the elderly continuously use medication, which can cause side effects. On the other hand, the tendency toward non-pharmacological treatment has recently increased, and developments have been achieved in non-pharmacological treatment methods.⁴ It has been reported that methods such as music therapy, eye mask, complementary therapies, massage, aromatherapy, and a foot bath are used to improve the sleep quality of elderly people with sleep problems.¹⁰ Foot baths are reported to facilitate falling asleep by affecting body temperature. Sleep quality may improve in patients whose falling asleep process becomes easier.¹¹⁻¹³ However, there are international studies examining sleep quality^{9, 14-19} or sleep latency²⁰ in the elderly. In Turkey, studies have been conducted on the effect of foot bath on sleep quality in cancer patients,²¹ individuals with Chronic Obstructive Pulmonary Disease²² and university students with

premenstrual syndrome,²³ but there has not been a study in which foot bath has been performed in healthy elderly individuals. Within the scope of this information, the effect of foot bath on sleep quality in healthy elderly individuals who grew up with Turkish culture was examined in this study. Within the framework of the positive results obtained from this study, it is expected that foot bath will also increase sleep quality in elderly individuals living in Turkey. In addition, the applicability and effectiveness of a non-pharmacological application such as foot bath on elderly individuals who grew up with Turkish culture was proven with this study.

AIM

The aim of this study was to investigate the effects of foot bath applied for 8 weeks on sleep quality in elderly people living in a rural area in Turkey.

Research hypothesis

H₁: Foot bath has a positive effect on the sleep quality of the elderly.

H₀: Foot bath does not have a positive effect on the sleep quality of the elderly.

METHODS

Type of Research

This study was carried out as a single-blind randomized single-blind, randomized controlled parallel-group study to investigate the effect of a foot bath on sleep quality in the elderly.

Place and Time of the Study

The data were collected between 1 May 2022 and 1 July 2022 in a State Hospital in Gümüşhane.

Population and Sample of the Study

The population consisted of acquaintances of the elderly (such as relatives, neighbors, or friends) aged 65 years and over of the patients who came to the Medical Clinic of a State Hospital in Gümüşhane between 1 May 2022 and 1 July 2022. Power analysis was performed to select the elderly to be sampled. The sample size was calculated as 36 (18 for each group) elderly in total for the two groups (foot bath group, control group) with an effect size of 1,000 and the power of the targeted test was 0.90 (90%) in the G*Power 3.1.9.6 program with the error of $\alpha=0.05$ and a reference to a previous study on the subject.²⁴ Considering the cases such as withdrawal from the study or death during the research, each group was increased and a total of 50 elderly individuals, 25 elderly people for each group, were recruited for the study (Figure 1). The study was registered on Clinical Trials (NCT05572554).

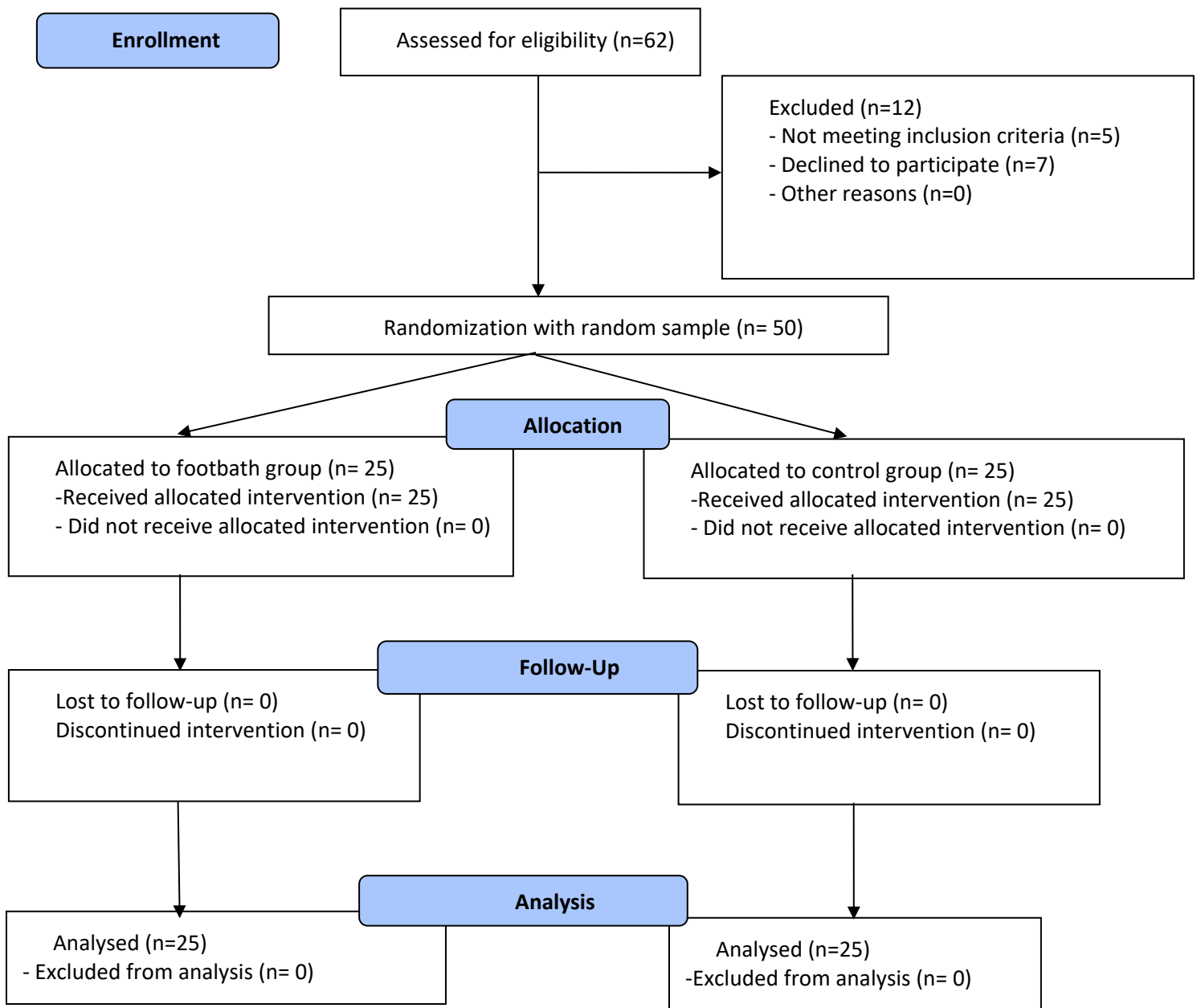


Figure 1. The Study CONSORT Flow Diagram

For patient randomization, the block randomization method was employed to maintain balance between the groups in terms of participant numbers. Given that an equal number of groups and probabilities were required within each block, block sizes of 8 participants were established, with 4 participants in the experimental group and 4 participants in the control group per block, in accordance with established literature. A random number table ranging from 1 to 70 was generated using Microsoft Excel to randomize the blocks. The study concluded once a sufficient number of blocks, corresponding to the total

number of sampled patients in the randomized blocks were completed.

In the study, which was planned as a *single-blind randomized controlled clinical trial*, the researcher who applied the data collection tools and the one who randomized the foot bath group, and the control group were different people to reduce bias.

Variables of the Study

Baseline and Independent variables of the study; The descriptive characteristics of the elderly (age, gender,

marital status, education level, occupation, income perception level, presence of chronic disease, presence of pain, health perception level) are the baseline variables and foot bath application is the independent variable.

Dependent variables of the study; The Pittsburgh Sleep Quality Index (PSQI) score of the elderly.

Inclusion Criteria

- Those aged 65 and over,
- Being literate,
- Performing activities of daily living,
- Not having problems with the sense organs (such as eyes, ears, skin),
- Not being paraplegic/hemiplegic,
- Not working the night shift,
- Having a mobile phone that can make video a call or having a relative with such a phone,
- No impairment in mental and cognitive functions (score of 24 or higher on the Standardized Mini Mental Test (SMTT); score of 21 or higher on the Montreal Cognitive Assessment (MOCA) Scale).

Exclusion Criteria

- Refusing to participate in the research,
- Having psychological disorders,
- Using complementary therapy to sleep,
- Having enuresis,
- Being bedridden or using a wheelchair,
- Having more than 10 years of diagnosis of diabetes or diabetes-related neuropathy.

Data Collection Tools

The data were collected using the “Elderly Information Form” and “PSQI”.

The Elderly Information Form: The form, created in line with the literature, includes 9 questions about the descriptive characteristics of the elderly (age, gender, marital status, education level, occupation, income perception level, presence of chronic disease, presence of pain, and health perception level).¹⁻¹⁰

The Pittsburgh Sleep Quality Index (PSQI): PSQI is an index that questions sleep quality, type, and severity of sleep disturbance in the last month in adults. 19 questions are answered by the person himself/herself, and 5 questions are answered by the person’s bedmate or people sleeping in the same room. The questions answered by the person to whom the index is applied are taken into consideration in the scoring, while the others answered by the bed/roommate are not taken into consideration. Seven subcomponents are assessed with 19 questions answered by the respondent: “subjective sleep quality (Component (C1))”, “sleep latency (C2)”, “sleep duration (C3)”, “habitual

sleep efficiency (C4)”, “sleep disturbances (C5)”, “use of sleeping medication (C6)” and “daytime dysfunction (C7)”. Each item in the index takes a value between 0 (no distress) and 3 (severe distress). The sum of the scores related to the seven sub-dimensions gives the total PSQI score. The score of each sub-dimension varies between 0 and 3, and the total PSQI score varies between 0-21. Sleep quality of those with a total score of 5 and below is considered “good”.²⁵⁻²⁶ The Turkish validity and reliability study of the PSQI was performed by Ağargün et al.²⁷ and the internal consistency coefficient was reported to be 0.80. In this study, the test-retest Cronbach alpha value of the PSQI was calculated as 0.903.

Data collection method

All the participants in the study were contacted by telephone and invited to the study. The data collection method of the study is presented below for all two groups.

Foot Bath Group

The elderly in this group were taught the foot bath practically one by one by the researcher at the pre-study meeting and were also given the “Foot Bath Information Brochure” and a “Personalized Water Thermometer”. The information/teaching continued until all the elderly in the group performed the foot bath correctly. The other researcher administered the “Elderly Information Form” and “PSQI” to all elderly people before the study using individual interviews lasting approximately 15 minutes and pen and paper method. The elderly were asked to soak their feet in the water in a marked plastic container with a depth of 10 centimeters and a temperature of 41-42°C for 20 minutes up to their ankles 50 minutes before normal sleeping hours every night for 8 weeks. Each elderly person was video-called by the researcher once a week to monitor their foot bath practices and to monitor whether the foot bath practice was performed correctly. In addition, the PSQI, which provides information about sleep quality, type, and severity of sleep disturbance, was applied to the elderly before the study (pretest), 4th week (interim measurement/1st measurement), and at the end of the study (8th week) for a total of 3 times during 8 weeks.

The Foot Bath Information Brochure: This brochure was created by the researcher and included information on the benefits of a foot bath and how to perform a foot bath (50 minutes before bedtime each night, the participants were to immerse their feet up to their ankles in a marked plastic container of water 10 centimeters deep and 41-42°C, measured with a water thermometer, for 20 minutes).

A Water Thermometer: It is a “Robitshop TP101” brand thermometer used to measure the degree of water used in the foot bath application of the elderly. The measurement

range of the thermometer is -50 to +300 °C and works with a 1.5 Volt button battery.

Control Group

No application was made to the elderly in this group. Only the PSQI, which gives information about sleep quality, type, and severity of sleep disturbance, was administered to the elderly before the study (pretest), at the 4th week (interim measurement/1st measurement), and at the end of the study (8th week) for a total of 3 times for 8 weeks.

Strengths and Limitations of the Study

Strengths of the Study: In our study, the application of foot bath with 41-42°C water for 8 weeks is the longest compared to the studies conducted with the same water temperature. This methodological difference is the strength of the study.

Ethical Considerations

Written institutional permission was obtained from Gümüşhane Provincial Health Directorate (dated 29/04/2022 and numbered E-51020271-044), and ethics committee permission was obtained from Gümüşhane University Scientific Research and Publication Ethics Committee (dated 27/04/2022 and numbered 2022/03) for a State Hospital. Verbal and written informed consent was obtained from the elderly involved in the study.

Data Analysis

The data were evaluated with the licensed *SPSS (Statistical Package for Social Sciences)* 23.0 package program. It is reported in the literature that non-parametric tests should be used in experimental studies when the number of subjects in the groups is less than 30 because the probability of fitting the data to the normal distribution will decrease.²⁸ Since the number of subjects in the groups (foot bath group=25, control group=25) was less than 30, the Chi-square test was used to compare categorical variables according to groups, and the Mann-Whitney U test was used to compare numerical variables according to groups. Friedman test in dependent groups and Wilcoxon Sign Test with Bonferroni correction were performed to evaluate changes over time. The Mann-Whitney U test with Bonferroni correction was used to determine the difference between the groups. The results were evaluated at a 95% confidence interval and significance level of $P<.05$.

RESULTS

In this study, the effect of a foot bath on sleep quality in elderly people aged 65 years and older was investigated. Table 1 shows the distribution of the descriptive information about the elderly according to the groups. There was no statistically significant difference between the foot bath group and the control group in terms of

Table 1. Distribution of Baseline Variables of The Elderly According to Groups (n=50)

Descriptive characteristics		Foot Bath Group (n=25)*	Control Group (n=25)*	Test Statistics; P
Age	$\bar{x} \pm SS$	68.68 $\pm$ 3.69	68.76 $\pm$ 3.30	Z=-0.383 ^b ; .702
	Median (Min-Max)	68 (65-81)	69 (65-81)	
Gender	Male	15 (60.0)	12 (48.0)	$\chi^2=0.725^a$; .395
	Female	10(40.0)	13(52.0)	
Marital status	Married	13 (52.0)	18 (72.0)	$\chi^2=2.122^a$; .145
	Single (Widow(er)/ Divorced)	12 (48.0)	7(28.0)	
Education level	Primary school/ Literate	9 (36.0)	12 (48.0)	$\chi^2=0.781^a$; .677
	Secondary/High school	8 (32.0)	6 (24.0)	
	Undergraduate and over	8 (32.0)	7 (28.0)	
Occupation	Housewife	7 (28.0)	10 (40.0)	$\chi^2=0.868^a$; .648
	Retired	10 (40.0)	9 (36.0)	
	Employed	8 (32.0)	6 (24.0)	
Perception of income	Income less than expenditure	10 (40.0)	7 (28.0)	$\chi^2=1.001^a$; .606
	Income equal to expenditure	8 (32.0)	11 (44.0)	
	Income more than expenditure	7 (28.0)	7 (28.0)	
Chronic disease	Yes	18 (72.0)	19 (76.0)	$\chi^2=0.104^a$; .747
	No	7 (28.0)	6 (24.0)	
Pain	Yes	15 (60.0)	16 (64.0)	$\chi^2=0.085^a$; .771
	No	10 (40.0)	6 (36.0)	
Health perception level	Good	9 (36.0)	5 (20.0)	$\chi^2=2.476^a$; .290
	Moderate	12 (48.0)	12 (48.0)	
	Bad	4 (16.0)	8 (32.0)	

*Percentage of columns was taken, ^aChi-square test $p<0.05$, ^bMann-Whitney U test $p<0.05$, Med; Median, Min; Minimum, Max; Maximum

gender, marital status, education level, occupation, income perception level, presence of chronic disease, presence of pain, health perception level, and mean age ($P>.05$) (Table 1).

Table 2 shows that as a result of the Friedman test, at least one of the median scores of subjective sleep quality (C1), use of sleeping medication (C6), daytime dysfunction (C7) components, and total PSQI measurements differed

between the foot bath and control groups ($P<.05$).

As a result of the Friedman test, it was found that at least one of the median scores of sleep latency (C2), sleep duration (C3), habitual sleep efficiency (C4) and sleep disturbance (C5) component measurements in the foot bath group differed depending on time ($P<.05$), but there was no statistically significant difference in the control group ($P>.05$) (Table 2).

Table 2. The Time-Dependent Differences in Pittsburgh Sleep Quality Index (PSQI) and Subcomponent Mean Scores of the Foot Bath and Control Group Elderly (n=50)

Component (C)		Foot bath group (n=25) Median (25.-75. Percentile)	Control Group (n=25) Median (25.-75. Percentile)
C1: Subjective sleep quality	Pretest	2.0 (2.0-3.0)	2.0 (1.5-3.0)
	1st measurement	2.0 (1.0-2.0)	2.0 (2.0-3.0)
	Posttest	1.0 (1.0-1.0)	2.0 (2.0-3.0)
	$\chi^2; P$	$\chi^2=35.343; <.001^*$	$\chi^2=6.703; .035^*$
C2: Sleep latency	Pretest	2.0 (2.0-3.0)	2.0 (1.5-3.0)
	1st measurement	2.0 (1.0-2.0)	2.0 (2.0-3.0)
	Posttest	1.0 (0.5-1.0)	2.0 (2.0-3.0)
	$\chi^2; P$	$\chi^2=38.675; <.001^*$	$\chi^2=1.786; P=0.409$
C3: Sleep duration	Pretest	2.0 (2.0-3.0)	2.0 (2.0-3.0)
	1st measurement	2.0 (1.0-2.0)	2.0 (2.0-3.0)
	Posttest	1.0 (0-1.0)	2.0 (2.0-3.0)
	$\chi^2; P$	$\chi^2=37.520; <.001^*$	$\chi^2=0.080; P=0.961$
C4: Habitual sleep efficiency	Pretest	2.0 (1.0-2.5)	2.0 (2.0-3.0)
	1st measurement	3.0 (3.0-3.0)	2.0 (2.0-3.0)
	Posttest	1.0 (0-1.5)	2.0 (2.0-3.0)
	$\chi^2; P$	$\chi^2=35.086; <.001^*$	$\chi^2=2.545; P=0.280$
C5: Sleep disturbances	Pretest	2.0 (1.0-2.0)	1.0 (1.0-2.0)
	1st measurement	1.0 (1.0-1.0)	2.0 (1.0-2.0)
	Posttest	1.0 (1.0-1.0)	2.0 (1.0-2.0)
	$\chi^2; P$	$\chi^2=23.286; <.001^*$	$\chi^2=0.889; P=0.641$
C6: Use of sleeping medication	Pretest	1.0 (0-2.0)	1.0 (0-2.0)
	1st measurement	0 (0-1.0)	1.0 (1.0-2.0)
	Posttest	0 (0-1.0)	2.0 (1.0-3.0)
	$\chi^2; P$	$\chi^2=15.872; <.001^*$	$\chi^2=11.231; .004^*$
C7: Daytime dysfunction	Pretest	2.0 (2.0-3.0)	2.0 (2.0-3.0)
	1st measurement	1.0 (1.0-2.0)	3.0 (2.0-3.0)
	Posttest	1.0 (0-1.0)	3.0 (2.0-3.0)
	$\chi^2; P$	$\chi^2=32.909; <.001^*$	$\chi^2=13.400; .001^*$
Total PSQI score	Pretest	14.0 (13.0-15.0)	13.0 (12.0-16.0)
	1st measurement	9.0 (8.0-11.5)	15.0 (13.5-16.0)
	Posttest	5.0 (4.0-8.0)	15.0 (14.0-17.0)
	$\chi^2; P$	$\chi^2=50.000; <.001^*$	$\chi^2=15.564; <.001^*$

*Friedman test $P<0.05$

According to the nonparametric Wilcoxon test pairwise to determine whether there was a significant difference between the Subjective Sleep Quality (C1) in the foot bath and control groups in Table 3, a statistically significant difference was found between the pretest and 1st measurement ($Z=-3.464; P=.001$), 1st measurement and posttest ($Z=-4.179; P<.001$), and 1st measurement and

posttest ($Z=-4.000; P<.001$) in the foot bath group (Bonferroni corrected $P<.017$). In the control group, there was no statistically significant difference between the mean ranks of the Subjective Sleep Quality (C1) of pretest and 1st measurement ($Z=-1.667; P=.096$), pretest and posttest ($Z=-2.138; P=.033$), 1st measurement and posttest ($Z=-1.342; P=.180$) (Bonferroni corrected $P>.017$) (Table 3).

Table 3. The Time-Dependent Differences in Pittsburgh Sleep Quality Index (PSQI) And Subcomponent Scores Between The Foot Bath and Control Groups (n=50)

Subcomponent		Foot bath group (n=25)		Control Group (n=25)		MWU		
		Z	P	Z	P	Measurement Difference	U	P
C1: Subjective Sleep Quality	Pretest-1.measurement	-3.464 ^b	.001*	-1.667 ^c	.096	-	-	-
	Pretest-Posttest	-4.179 ^b	<.001*	-2.138 ^c	.033	-	-	-
	1.measurement-Posttest	-4.000 ^b	<.001*	-1.342 ^c	.180	-	-	-
C6: Use of sleeping medication	Pretest-1. measurement	-3.162 ^b	.002*	-1.155 ^c	.248	-	-	-
	Pretest-Posttest	-2.961 ^b	.003*	-2.461 ^c	.014*	(PRT-POT)	140.5	<.001**
	1.measurement-Posttest	-1.897 ^b	.058	-3.051 ^c	.002*	-	-	-
C7: Daytime Dysfunction	Pretest-1. measurement	-4.146 ^b	<.001*	-3.000 ^c	.003*	(PRT-1)	56.0	<.001**
	Pretest-Posttest	-4.045 ^b	<.001*	-2.646 ^c	.008*	(PRT-POT)	57.5	<.001**
	1.measurement-Posttest	-3.578 ^b	<.001*	-1.000 ^b	.317	-	-	-
Total PSQI score	Pretest-1. measurement	-4.391 ^b	<.001*	-1.712 ^c	.087	-	-	-
	Pretest-Posttest	-4.384 ^b	<.001*	-3.119 ^c	.002*	(PRT-POT)	1.5	<.001**
	1.measurement-Posttest	-4.387 ^b	<.001*	-2.754 ^c	.006*	(1-POT)	3.0	<.001**

*Wilcoxon test (Bonferroni corrected $P < 0.017$); MWU: Mann-Whitney U; **Mann-Whitney U test and $p < 0.05$; b: Negative rankings; c: Positive rankings; PRT: Pretest; POT: Posttest

According to the results of the nonparametric Wilcoxon test pairwise comparison, a statistically significant difference was found between the mean ranks of the pretest and 1st measurement ($Z = -3.162$; $P = .002$), and pretest and posttest ($Z = -2.961$; $P = <.003$) of the Use of Sleeping Medication (C6) in the foot bath group (Bonferroni corrected $P < .017$); however, no statistically significant difference was found between the mean ranks of the 1st measurement and posttest ($Z = -1.897$; $P = .058$) (Bonferroni corrected $P > .017$). In the control group, there was a statistically significant difference between the mean ranks of the pretest and posttest ($Z = -2.461$; $P = .014$), 1st measurement and posttest ($Z = -3.051$; $P = .002$) of the Use of Sleeping Medication (C6) (Bonferroni corrected $P < .017$), but there was no statistically significant difference between the mean ranks of the pretest and 1st measurement ($Z = -1.155$; $P = .248$) (Bonferroni corrected $P > .017$) (Table 3). The result of the nonparametric Mann-Whitney U test, which was applied to determine whether the Use of Sleeping Medication (C6) scores of the elderly differed significantly according to the foot bath and control groups, showed a statistically significant difference between the groups at $P < .05$ level in favor of the foot bath group (Table 3).

According to the nonparametric Wilcoxon test pairwise comparison results in Table 3, there was a statistically significant difference between the mean ranks of Daytime Dysfunction (C7) in the pretest and 1st measurement ($Z = -4.146$; $P < .001$), pretest and posttest ($Z = -4.045$; $P < .001$), 1st measurement and posttest ($Z = -3.578$; $P < .001$) in the foot bath group (Bonferroni corrected $P < .017$). In the control group, there was a statistically significant difference

(Bonferroni corrected $P < .017$) between pretest and 1st measurement ($Z = -3.000$; $P = .003$), pretest and posttest ($Z = -2.646$; $P = .008$) of Daytime Dysfunction (C7) rank means, however, there was no statistically significant difference between the 1st measurement and posttest ($Z = -1.000$; $P = .317$) Daytime Dysfunction (C7) mean scores (Bonferroni corrected $P > .017$) (Table 3). According to the result of the nonparametric Mann-Whitney U test applied to determine whether the Daytime Dysfunction (C7) scores differed significantly between the groups, a statistically significant difference was found at the $P < .05$ level in favor of the foot bath group (Table 3).

According to the pairwise comparison results of the nonparametric Wilcoxon test, a statistically significant difference was found between the mean ranks of the total PSQI score of the pretest and 1st measurement ($Z = -4.391$; $P < .001$), pretest and posttest ($Z = -4.384$; $P < .001$), 1st measurement and posttest ($Z = -4.387$; $P < .001$) of the foot bath group (Bonferroni corrected $P < .017$). While there was a statistically significant difference between the mean ranks of the total PSQI score of the control group in the pretest and posttest ($Z = -3.119$; $P = .002$), 1st measurement and posttest ($Z = -2.754$; $P = .006$) (Bonferroni corrected $P < .017$), there was no statistically significant difference between the mean ranks of the pretest and 1st measurement ($Z = -1.712$; $P = .087$) (Bonferroni corrected $P > .017$) (Table 3). According to the result of the nonparametric Mann-Whitney U test applied to determine whether the Total PSQI scores differed significantly between the groups, a statistically significant difference was found at the $p < 0.05$ level in favor of the foot bath group (Table 3).

DISCUSSION

In this study, sleep quality scores were similar before foot bath application. This is thought to be due to the normal distribution of the data. In the literature, foot baths are reported to facilitate falling asleep by affecting body temperature. There is a negative relationship between core body temperature and sleep. The decrease in core body temperature before sleep caused by a foot bath promotes the sleep process and improves sleep quality. A foot bath may indirectly improve sleep quality by improving the parameters required for a comfortable sleep (blood pressure, heart rate, sympathetic activity, decreased anxiety, etc.).¹¹⁻¹³ In our study, the sleep quality of the elderly who underwent a foot bath increased significantly for 8 weeks and the PSQI score decreased. In an experimental study by Armat et al., it was reported that sleep quality increased without any difference between the elderly groups who received foot baths for 10 minutes (min) every day for 2 weeks with 37°C and 40°C water,¹⁶ which is consistent with our study. Likewise, in two studies conducted in Iran, it was found that a foot bath significantly decreased the PSQI score in the elderly.^{9, 29} It was determined with polysomnographic results in the study by Morin et al.³⁰ that nonpharmacological applications led to a decrease in the duration of falling asleep and the number of awakenings. A randomized controlled study conducted on 69 elderly men found that foot baths at 41-42 degrees for 6 weeks improved sleep quality.⁹ In a study, it was determined that a foot bath applied for 20 minutes with 40-degree water on 2 evenings for 1 week improved the sleep quality of 20 female Filipino elderly.¹⁵ In another semi-experimental study, the effectiveness of foot bath on sleep quality was investigated in 60 elderly individuals. Patients were given foot baths with hot water (43-46 degrees) for 10 minutes per day for 7 days. As a result of the aforementioned study, it was reported that foot baths with hot water increased sleep quality in elderly individuals.¹⁹ Again, it is thought that sleep quality differed in the control group patients as expected in our study and this is due to the fact that the majority of the married elderly in the control group engaged in activities that could affect their sleep.

In the reviewed literature, two studies with different scales were found in which the effect of a foot bath on sleep quality was evaluated.^{20, 31} Rahmani et al.³¹ also reported that a foot bath (with 40 °C water) provided improvement in the "Verran and Snyder-Halpern Sleep Scale" and improved sleep quality in their experimental study in elderly people over 60 years of age.³¹ Using actigraphy to measure sleep quality, Jo Kim et al.²⁰ found that a foot bath applied at different temperatures (40°C for the

experimental group and 36.5°C for the placebo group) for 30 min per day improved sleep quality in South Korean elderly living in nursing homes, but the effect of a foot bath decreased after the 3rd week.²⁰ We speculate that the reason for this result may be due to the wheelchair or bed-dependent elderly people or different factors that may trigger insomnia in their study.²⁰

In this study, foot baths decreased sleep latency throughout the application in the elderly. In two literature studies analyzed, unlike our study, it was reported that foot baths did not make any change in sleep latency.^{20, 32} In the study of Jung,³² the lack of a difference in sleep latency may have been due to the fact that the elderly waited for one hour after a foot bath.

In another study, it was reported that sleep latency decreased similar to our study.¹⁷ Sung and Tochihara³³ noted that nonpharmacological methods increased the sleep quality of individuals and decreased the time to fall asleep, and there were differences between the groups between the 2nd and 3rd stages of sleep.³³

In old age, sleep duration decreases to 5-7 hours, falling asleep time prolongs, and phases 3 and 4 shorten.³⁴ In our study, foot baths caused a reduction in the sleep duration of the elderly contrary to what was expected. In the studies reviewed, it was reported that foot baths^{18, 24} and whole-body baths^{35, 36} did not increase slow wave sleep in the elderly with insomnia. In our study, the decrease in sleep duration in the elderly may have resulted from the fact that they woke up rested in a shorter time due to improved sleep quality. In a study conducted by Namba et al.³⁷ with elderly intensive care patients, it was stated that the elderly slept more in the evening when a foot bath was performed in accordance with the literature. However, it was found that there was no significant difference in "Rapid Eye Movement" sleep on the days of a foot bath.³⁷

In our study, foot baths decreased sleep disturbance in the elderly. In a relevant study, it was reported that there was no significant change in sleep disturbance scores although the sleep quality of the elderly increased with foot bath application, which was explained by the fact that the elderly could not give correct answers as they had difficulty evaluating the scale questions.²⁰ In another study, it was found that sleep disturbance decreased like our study.²⁴ In an experimental study, 46 elderly people were given a foot bath with water at 41-42 degrees for 6 weeks, and as a result of the study, a significant improvement was reported in the elderly's sleep duration and total sleep quality.¹⁴

Limitations of the Study

Limitations of the study include the fact that the intervention, although supervised, was implemented by

the subjects and the characteristics of the data collection (based on self-reporting).

In light of the findings of the study, it was concluded that foot baths had a positive effect on the sleep quality of the elderly, increased subjective sleep quality, decreased sleep latency, sleep duration, use of sleeping medication, and daytime dysfunction. However, a foot bath increased the habitual sleep efficiency in the elderly up to the 4th week but lost its effect after the 4th week and decreased. Within the framework of the results obtained from this study, it may be recommended that sleep quality be monitored for a longer period in elderly individuals and compared with other non-pharmacological treatment methods. However, it is recommended that the effectiveness of foot baths be tested in other sample groups, at different water temperatures, in healthy or patient groups and even compared with different applications.

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Hasta Onamı: Çalışmaya katılan yaşlılardan sözlü ve yazılı aydınlatılmış onam alındı.

Hakem Değerlendirmesi: Dış bağımsız.

Yazar Katkıları: Fikir- HD,AC,SH; Tasarım-HD,AC,SH; Denetleme-SH; Kaynaklar-HD,AC,SH; Veri Toplanması ve/veya İşlemesi-HD,AC; Analiz ve/veya Yorum-HD,AC,SH; Literatür Taraması-HD,AC,SH; Yazıyı Yazan-HD,AC; Eleştirel İnceleme-SH.

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Ethics Committee Approval: Ethics committee approval was received from Gümüşhane University Scientific Research and Publication Ethics Committee (Date: 27.04.2022, Number: 2022/3).

Informed Consent: Verbal and written informed consent was obtained from the elderly involved in the study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept -HD,AC,SH; Design-HD,AC,SH; Supervision-SH; Resources-HD,AC,SH; Data Collection and/or Processing-HD,AC; Analysis and/or Interpretation-HD,AC,SH; Literature Search-HD,AC,SH; Writing Manuscript-HD,AC; Critical Review-SH.

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Learning Experiences of Nurses Regarding COVID-19 During the Pandemic and Affecting Factors

Hemşirelerin Pandemi Sürecinde COVID-19'a Yönelik Öğrenme Deneyimleri ve Etkileyen Faktörler

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ABSTRACT

Objective: The aim of the study is to determine the learning experiences of nurses regarding COVID-19 during the pandemic and identify the factors influencing these experiences.

Methods: This is a cross-sectional and descriptive study. The study was conducted with 516 nurses working in health institutions in Turkey. The data for the research were collected online using an information form developed by the researchers in February-March 2021, in accordance with the literature.

Results: Of the nurses participating in the study, 83.9% were female, 60.7% were single, 81.98% belonged to Generation Y, and 43.60% had 1-4 years of professional experience. The research findings indicated that nurses relied more on national resources and observational methods to acquire information during the pandemic. It was observed that the high workload and nurse shortage made it challenging for them to implement the knowledge they gained. The nurses' age, professional experience, education level, and the institution they worked for were identified as factors influencing their learning experiences.

Conclusion: It is thought that determining the way nurses follow in the development of their professional knowledge and skills, which learning resources they use, which learning path they prefer, what difficulties they have in applying what they have learned, and the factors affecting their learning experiences will lead to the planning of in-service training activities.

Keywords: Education, continuing, COVID-19, nursing, professional

ÖZ

Amaç: Çalışmada hemşirelerin pandemi sürecindeki, COVID-19'a yönelik öğrenme deneyimleri ve bu deneyimlerini etkileyen faktörlerin belirlenmesi amaçlanmaktadır.

Yöntemler: Çalışma kesitsel ve tanımlayıcıdır. Çalışma Türkiye'de sağlık kurumlarında çalışan 516 hemşire ile gerçekleştirilmiştir. Araştırmanın verileri Şubat-Mart 2021 tarihleri arasında, araştırmacılar tarafından literatür doğrultusunda geliştirilen bilgi formu ile online olarak toplanmıştır.

Bulgular: Çalışmaya katılan hemşirelerin %83,9'u kadın, %60,7'si bekar, %81,98'i Y kuşağıydı, %43,60'ı 1-4 yıllık mesleki deneyime sahipti. Çalışma sonuçları hemşirelerin pandemi sürecinde daha çok ulusal kaynaklardan ve gözlem yoluyla bilgi edindiğini gösterdi. Hemşirelerin iş yükünün fazla olması, hemşire eksikliği nedeni ile öğrendikleri bilgiyi uygulamaya aktarmada güçlük yaşadığı saptandı. Hemşirelerin yaşı, mesleki deneyimi, eğitim düzeyi ve çalıştığı kurumun öğrenme deneyimlerini etkilediği belirlendi.

Sonuç: Hizmet içi eğitim etkinliklerinin planlanmasında hemşirelerin mesleki bilgi ve becerilerinin geliştirilmesinde izledikleri yolun, hangi öğrenme kaynaklarını kullandıklarının, hangi öğrenme yolunu tercih ettiklerinin, öğrendiklerini uygulamada ne gibi zorluklar yaşadıklarının ve öğrenme deneyimlerini etkileyen faktörlerin belirlenmesinin önemli olacağı düşünülmektedir.

Anahtar Kelimeler: COVID-19, eğitim, hemşirelik, profesyonel, sürekli

INTRODUCTION

The COVID-19 pandemic has become a worldwide disaster that has never been experienced before, deeply affecting the health, economic and social systems of all countries. Among these systems, health workers and nurses have been the most affected by the healthcare system. During the pandemic, nurses found themselves managing a disease they had never experienced before, witnessing changes in care procedures. Some nurses took on the responsibility of caring for COVID-19 patients without completing their orientation processes and were exposed to a high risk of infection.¹

According to the report of the Turkish Nurses Association, one of the challenges faced by nurses working to provide qualified and safe care during the pandemic is the obligation to work in unfamiliar units.² Particularly, existing clinics have been closed to meet the needs of COVID-19 patients, and pandemic clinics and hospitals have been established.²⁻⁴ In this process, nurses have been pulled into pandemic clinics, emergency services, and intensive care units; however, there has been insufficient time and training opportunities to work in these units. The uncertainty and lack of preparation for effective work in special units like pandemic clinics and intensive care have led to fear and panic among nurses.²⁻⁶ Additionally, issues such as changes in routine practices, uncertainty about the responsibility for procedures, and the desire of other healthcare workers afraid of infection to delegate tasks to nurses have also arisen.²⁻⁶

During this process, nurses have been under intense stress due to various stressors such as new infection management approaches, the necessity to cope with a lack of personal protective equipment, providing care to infected colleagues, fear of transmitting the infection to family members, and inadequate training and information about the process.⁷⁻⁹ During the pandemic, the psychological burden on nurses was significant. Studies show that the combination of new infection management protocols, insufficient personal protective equipment (PPE), and the emotional strain of caring for infected colleagues led to increased anxiety and fear among nursing staff.⁸ Nurses reported feelings of panic and uncertainty, particularly when taking on responsibilities in high-risk environments without adequate training.⁷⁻¹⁰ This situation necessitates the establishment of appropriate education and support systems for the management of nurses' experiences during this process.^{9,10}

Furthermore, the pandemic has highlighted the need for robust educational frameworks to prepare nurses for emergencies. The literature reveals a significant gap in

studies focusing on nurses' learning experiences during the pandemic and suggests a need for targeted research to inform future educational policies.^{7,11} It is thought that nurses as adult individuals exhibit learning behaviors in line with adult learning principles, and adult learning principles emphasize that nurses, as adult learners, benefit from their experiences and readiness to learn, which could be crucial for adapting to the rapidly changing healthcare environment.^{4,7,12} By understanding nurses' learning experiences during this crisis, healthcare institutions can better formulate in-service training programs that address the specific challenges faced during pandemics.^{7,8,11,12}

Determining the learning experiences of nurses during the pandemic will provide guidance on how hospitals should formulate/plan their training policies in emergency situations. However, when the literature is examined, it is observed that studies on nurses' learning experiences are quite limited. With this perspective the research was carried out to determine the learning experiences of nurses regarding COVID-19 during the pandemic and identify the factors influencing these experiences. It is believed that the data obtained from the study will not only be informative for the pandemic period but will also serve as a guide in planning all in-service training activities.

AIM

It was aimed to determine the learning experiences of nurses regarding the COVID-19 during the pandemic and identify the factors influencing these experiences.

This study addresses the following questions:

- What are nurses' learning experiences in terms of COVID-19?
- Do the learning experiences of nurses differ according to their socio-demographic characteristics?

METHODS

Study Design

This is a cross-sectional and descriptive study.

Population and Study of the Sample

The population of the study consisted of nurses working in medical institutions in Turkey. According to the data of the Ministry of Health within the 2019 Health Statistics Yearbook, there were 198.103 nurses in Türkiye.¹³ Using the OpenEpi sample size calculator application developed by the Centers for Disease Control and Prevention (CDC), the sample size was calculated as at least 500 with a 95% confidence interval and 5% error rate.¹⁴ In the study, there was no sample selection. The data collection process was ended when the targeted sample size was reached. As a result, the study was completed with 516 nurses.

Inclusion criteria:

- Being employed as a nurse in health institutions in Türkiye.
- To fill out the data collection form completely.

Data Collection Tool

Since there is no valid and reliable measurement tool for nurses' learning experiences regarding COVID-19, the data collection form has been developed by the researchers in line with the literature. The online questionnaire form consisted of two sections.

The first section consisted of 11 items questioning participants' sociodemographic data (age, gender, marital status, learning status, etc.).

In the second part of the form, there are 23 items (I) about learning experiences prepared by the researchers in line with the literature.¹⁵⁻²² The learning experiences in terms of COVID-19 were reviewed under the following three titles: 1-Preferred learning materials and learning styles in learning information about COVID-19 (I 1- I 9), 2-Knowledge and skills regarding COVID-19 (I 10- I 16), 3- Difficulties experienced in learning process in terms of COVID-19 (I 17- I 23). Participants evaluate each statement between 1 and 5 points (1-Does not define me at all, 5-Define me very well). Participants' level of agreement with each statement is given in percentages. Before applying the prepared questionnaire form, language and content validity was ensured by taking expert opinion from five experts in the field of nursing. The Davis Technique was utilized in the evaluation of experts' opinions regarding items.²³ To ascertain the coherence of the items and determine the clarity of expressions, experts were requested to rate each item on a scale of 1-4. The number of experts assigning scores of 3 and 4 on the scale was divided by the total number of experts to calculate the Content Validity Index (CVI). Content Validity Indices (CVIs) of items between 0.85 and 1.00 were considered appropriate. It was found that the content validity indexes (CGI) of the items were between 0.85-1.00 and were higher than the generally accepted standard level (0.80 and above). Experts agreed on all scale items. A pilot study (n=20) was conducted with the prepared form. At the end of the pilot study, no changes were made to the form, and the nurses who participated in the pilot study were not included in the study group. The Cronbach alpha value of the created questionnaire was 0.81. Cronbach's alpha value being over 0.7 indicates that the reliability of the data collection tool is at a good level.²⁴

Data Collection

During the COVID-19 pandemic, the data collection tool has

been transferred to an online platform to reach a larger audience. In the first section of the created form, a text was formulated containing the researcher's name, the purpose of the research, its duration, the anticipated number of participants, information that personal data of participants will not be collected, details on how the data obtained from the study will be used, and the methods for storing and destroying the data. Participants were asked whether they agreed to participate in the study. Those who agreed to participate were granted access to the entire data collection tool. Participants who indicated that they did not agree to participate were denied access to the data collection tool. Response submissions were closed to prevent one person from providing multiple responses. Data were collected between February and March 2021. Participants were reached through their social media accounts (Twitter, Instagram, Facebook, Telegram, WhatsApp groups, etc.). The online questionnaire form was shared on the relevant sites, and nurses were asked to complete the form. After achieving the targeted sample number, the online questionnaire was closed.

Statistical Analysis

Statistical Package for the Social Sciences (IBM SPSS Corp., Armonk, NY, USA) version 22 was used to analyze the data. Data analysis was performed using mean, standard deviation, frequency, percentage and Chi-square. The significance level was accepted as <.01.

Ethical Approval

This study was approved by the İstanbul University-Cerrahpaşa Social and Human Sciences Research Ethics Committee (05.01.2021-2020/284). Informed consent for participation was obtained through an online survey. The informed consent section regarding the study was present on the first page of the online survey. Selecting the relevant statement in this section was considered as giving consent, and the form was then opened for access.

RESULTS

In the study, the age of nurses was classified according to generations. Those born between 1965 and 1979 are grouped as the X generation, those born between 1980 and 1994 as the Y generation, and after 1995 as the Z generation.¹³ 81.98% of the participants are in the Y generation and the average age of the nurses is 30.77±8.0 (min:20-max:59) years. 43.60% of the nurses have 1-4 years of experience and the average professional experience is 8.68±8.46 (min: less than 1 year-max: 41) years. The characteristics of the nurses are shown in Table 1 in detail.

Table 1. Nurses' Introductory Characteristics (n=516)

Characteristics		n	%
Avg. Age 30.77±8.0 (min:20-max:59)	Generation X	73	14.15
	Generation Y	423	81.98
	Generation Z	20	3.87
Avg. Professional Experience 8.68±8.46 (min: less 1 year-max: 41)	Less than 1 year	45	8.72
	1-4 years	225	43.60
	5-10 years	80	15.50
	11-15years	57	11.05
	More than 16 years	109	21.12
Gender	Female	433	83.9
	Male	83	16.1
Marital Status	Single	313	60.7
	Married	203	39.3
Having a child	Yes	164	31.8
	No	352	68.2
Educational Status	High School's Degree	51	9.9
	Bachelor's Degree	318	61.6
	Master's Degree	147	28.5
Place of Employment	State	348	64.7
	Private	90	17.4
	University	78	15.1
Service unit	Service/Inpatient Service	158	30.6
	Intensive Care	138	26.7
	Administrative unit	53	10.3
	Emergency room	42	8.1
	COVID-19 Clinic	42	8.1
	Operating room	33	6.4
	Family health center	19	3.7
	COVID-19 intensive care	15	2.9
	Other*	16	3.2
Change of unit during the pandemic	Yes	238	46.12
	No	278	53.88
Chronic disease history in the family	No	173	33.5
	Himself/herself	5	1.0
	Partner	14	2.7
	1st degree relative	324	62.8
COVID-19 Diagnosis/Treatment	No	358	69.4
	Treatment at home	139	26.9
	Inpatient treatment	19	3.7

*Polyclinic, laboratory, and COVID-19 vaccination unit, Avg; Average, Min; Minumum, max; maximum

Nurses' Learning Experiences during the COVID-19 Pandemic

The results regarding the COVID-19 related learning experiences of nurses during the pandemic are presented in Table 2. *Preferred learning materials and learning styles in learning information about COVID-19* were examined, and results indicated that observations (27.7%), national scientific resources (25.6%), international scientific resources (25%), and guidelines from the Ministry of Health (22.1%) were utilized most.

When nurses' knowledge and skills regarding COVID-19 were examined, it was seen that nurses were most knowledgeable about infection routes (52.7%), symptoms (50.0%) and diagnostic methods (46.5%). Difficulties experienced in learning process in terms of COVID-19 were examined, and results demonstrated that nurses had difficulties practicing what they learned due to heavy workloads (19.6%), an insufficient number of nurses (15.7%), and the uncertainty in the progress of COVID-19 (8.3%). The statement "I did not have sufficient time to gain new information in the COVID-19 pandemic" had the lowest response rate (5.6%).

Comparison of Nurses' Introductory Characteristics and Learning Experiences

There was no significant difference between the gender of the participants and their learning experiences ($P>.01$). A significant difference was found between the age and preferred learning materials and learning styles in learning information about COVID-19 ($P<.01$). It has been determined that the Y generation learns the information about COVID-19 mostly from international scientific resources, and they prefer the observation and trial-and-error method less than the X and Z generations (Table 3).

There was no significant difference between generations in terms of being informed about COVID-19 ($P>.01$). When the difficulties experienced by nurses in the learning process during the pandemic and age are examined, research findings have shown that nurses from Generation Y experienced more difficulties in learning during the COVID-19 process ($P<.01$) (Table 3).

When the findings of the nurses are examined according to their professional experience, it is seen that the nurses working for 1-4 years are more likely to learn about Covid -19 from national and international scientific resources, the Ministry of Health guidelines, and by observing and trial and error method (Table 3).

When the difficulties experienced by nurses in the learning process during the pandemic and professional experience are examined, the nurses working for 1-4 years experienced more difficulties in learning during the COVID-19 process ($P<.01$) (Table 3).

The learning experiences of the nurses regarding the COVID-19 process were compared according to their educational status and the institution they work (Table 4). It has been seen that the nurses who have a bachelor's degree learn the information about COVID-19 mostly from national and international scientific resources, Ministry of Health guidelines and they prefer the observation ($P<.01$).

Table 2. Nurses' Learning Experiences in terms of COVID-19 (n=516)

Learning Experiences		Does not define me at all		Doesn't define me		It kind of defines me		Defines me		Define me at al	
		n	%	n	%	n	%	n	%	n	%
Preferred learning materials and learning styles in learning information about COVID-19	I 1. I learned the information related to COVID-19 from national scientific resources.	24	4.7	54	10.5	138	26.7	168	32.6	132	25.6
	I 2. I learned the information related to COVID-19 through observation.	46	8.9	57	11.0	110	21.3	160	31.0	143	27.7
	I 3. I learned the information related to COVID-19 from the guidelines of the Ministry of Health.	36	7.0	50	9.7	137	26.6	179	34.7	114	22.1
	I 4. I learned the information related to COVID-19 from international scientific resources.	43	8.3	64	12.4	134	26.0	146	28.3	129	25.0
	I 5. I learned the information related to COVID-19 from references such as social media, TV, or written media.	40	7.8	54	10.5	146	28.3	174	33.7	102	19.8
	I 6. I learned the information related to COVID-19 from the nursing literature and websites.	51	9.9	54	10.5	122	23.6	200	38.8	89	17.2
	I 7. I learned the information related to COVID-19 from training conducted in the institution.	94	18.2	69	13.4	141	27.3	123	23.8	89	17.2
	I 8. I learned the information related to COVID-19 from the WHO website.	115	22.3	86	16.7	137	26.6	112	21.7	66	12.8
	I 9. I learned the information related to COVID-19 through the trial and error method.	223	43.2	89	17.2	89	17.2	72	14.0	43	8.3
Knowledge and skills regarding COVID-19	I 10. I have sufficient knowledge about the ways of infection regarding COVID-19.	5	1.0	5	1.0	37	7.2	197	38.2	272	52.7
	I 11. I have sufficient knowledge about the symptoms of COVID-19.	3	0.6	9	1.7	41	7.9	205	39.7	258	50.0
	I 12. I have general knowledge about COVID-19.	5	1.0	7	1.4	56	10.9	220	42.6	228	44.2
	I 13. I have sufficient knowledge about the diagnostic methods regarding COVID-19.	9	1.7	13	2.5	60	11.6	194	37.6	240	46.5
	I 14. I have sufficient knowledge about the treatment process of COVID-19.	4	0.8	21	4.1	106	20.5	178	34.5	207	40.1
	I 15. I have sufficient skills about the care for a COVID-19 patient	21	4.1	44	8.5	90	17.4	162	31.4	199	38.6
	I 16. I have sufficient knowledge about the care for a COVID-19 patient	16	3.1	46	8.9	96	18.6	176	34.1	182	35.3
Difficulties experienced in learning process in terms of COVID-19	I 17. I had difficulties practicing the information I gained as my workload was heavy.	89	17.2	64	12.4	131	25.4	131	25.4	10	19.6
	I 18. I had difficulties practicing the information I gained owing to the insufficient number of nurses.	110	21.3	93	18.0	124	24.0	108	20.9	81	15.7
	I 19. I had difficulties learning owing to the uncertainties regarding COVID-19.	80	15.5	95	18.4	187	36.2	11	21.5	43	8.3
	I 20. I had difficulties practicing the information I gained owing to fears of infection.	138	26.7	106	20.5	127	24.6	96	18.6	49	9.5
	I 21. I had difficulties accessing up-to-date and primary resources regarding COVID-19.	131	25.4	134	26.0	140	27.1	74	14.3	37	7.2
	I 22. I did not have sufficient time to gain new information in the COVID-19 pandemic.	133	25.8	139	26.9	142	27.5	73	14.1	29	5.6
	I 23. I had difficulties practicing the information I gained as I did not have sufficient equipment.	153	29.7	113	21.9	124	24.0	88	17.1	38	7.4

I; Item

Table 3. Chi-Square Analysis on Comparison of Nurses' Entry Characteristics and Learning Experiences (n=516)

Learning Experiences	Age			Chi-Square	P	Professional Experience					Chi-Square	P
	Generation X	Generation Y	Generation Z			Less than 1 year	1-4 years	5-10 years	11-15 years	More than 16 years		
I 1					.130	7.3%	37.7%	19.3%	12.0%	23.7%	23.692	<.001*
I 2	8.2%	86.8%	5%	26.591	.003*	9.2%	48.5%	15.5%	11.9%	14.9%	27.666	<.001*
I 3					.320	8.2%	38.9%	16.4%	10.2%	26.3%	19.353	.002*
I 4	17.1%	81.8%	1.1%	15.521	<.001*	6.2%	40.4%	17.5%	11.3%	24.7%	16.824	.004*
I 5					.470							.602
I 6	13.5%	85.0%	1.5%	15.892	.037*							.049
I 7					.080							.280
I 8					.189							.203
I 9	5.2%	88.7%	6.1%	22.648	.002*	6.1%	59.1%	14.8%	12.2%	7.8%	35.765	<.001*
I 10					.350	8.7%	43.6%	15.5%	11.0%	21.1%	28.067	.031*
I 11	14.1%	82%	3.9%	18.420	.018*							.097
I 12					.118							.078
I 13					.079							.073
I 14	10%	85.5%	4.5%	17.413	.026*							.229
I 15					.443	5.5%	45.7%	16.9%	11.1%	20.8%	17.399	.007*
I 16					.068							.095
I 17	8.2%	87.1%	4.7%	18.373	<.001*	6.5%	56.0%	16.8%	6.9%	13.8%	48.219	<.001*
I 18	9.0%	86.2%	4.8%	14.652	<.001*	8.5%	52.9%	15.9%	7.9%	14.8%	22.805	<.001*
I 19	8.4%	87.0%	4.5%	13.357	.002*	6.5%	47.4%	19.5%	9.7%	16.9%	17.481	<.001*
I 20					.068	7.6%	49.0%	20.0%	11.0%	12.4%	17.108	.003*
I 21					.175	3.6%	55.0%	20.7%	3.6%	17.2%	28.134	.006*
I 22	3.9%	90.2%	5.9%	14.599	<.001*	6.9%	48.0%	22.5%	10.8%	11.8%	20.941	.002*
I 23	7.1%	90.5%	2.4%	10.872	<.001*	5.6%	49.2%	23.0%	9.5%	12.7%	19.608	<.001*

*<.05: statistically significant, I; Item

There was a significant difference between nurses' educational status and the items they stated to have sufficient knowledge about symptoms, sufficient knowledge about patient care and skills ($P<.01$). Nurses who have a bachelor's degree noted that they had more knowledge and skills about the symptoms of the disease and the care for COVID-19 patients (Table 4).

When the difficulties experienced by nurses in the learning process during the pandemic and nurses' educational status are examined, significant differences were found between nurses' educational status and difficulties in having time to gain new information during the COVID-19, heavy workload, practicing the information due to fears of infection ($P<.01$) (Table 4).

There was a significant difference between nurses' workplace and preferred learning materials and learning styles in learning information about COVID-19 ($P<.01$). Nurses who were working in state hospitals stated that they benefited more from international scientific resources and training conducted in hospitals on COVID-19 (Table 4).

A significant difference was found between nurses' workplace and experienced by nurses in the learning process during the pandemic ($P<.01$). Nurses working in

state hospitals stated that they had more difficulties in learning during the COVID-19 process due to heavy workload, insufficient number of nurses, fear of infection, accessing up-to-date and primary sources and insufficient time to gain new information regarding COVID-19 (Table 4).

DISCUSSION

This study assessed nurses' learning experiences, and the data were discussed in line with the literature. Nurses were aged between 20 and 59 years and represented different generations. The professional experience periods also show a wide range from 1 year to 41 years. The working group has a rich and colorful profile from novice nurses to experienced nurses.

They utilized international scientific references, observation, and guidelines from the Ministry of Health the most to learn about COVID-19. The literature indicates that nurses make efforts to gain information about the fight against the pandemic and care for COVID-19 patients from guidelines and studies, and they gain information from observations and the trial-and-error method.²⁵ Nurses also selected the method of observation to gain information, which suits the process of experimental learning; observing and supervising current experiences is related to the

Table 4. Chi-Square Analysis of Nurses' Learning Experiences About COVID-19 According to Their Educational Levels and Workplaces (n=516)

Learning Experiences	Education status					Workplace				
	High school	Bachelor's Degree	Master's Degree	Chi-Square	P	State	University	Private	Chi-Square	P
I 1	6.3%	57.3%	36.3%	26.829	<.001*	67.4%	15.1%	17.5%	17.168	.028*
I 2	11.9%	61.7%	26.4%	13.315	.001*	59.4%	16.1%	24.5%	17.280	.027*
I 3	7.2%	54.9%	37.9%	31.411	<.001*					.276
I 4	6.9%	56.0%	37.1%	24.353	<.001*	65.1%	19.6%	15.3%	11.814	<.001*
I 5					.221					.072
I 6	9.3%	55.7%	34.9%	6.186	.001*					.340
I 7					.056	61.3%	12.3%	26.4%	20.644	<.001*
I 8					.098					.775
I 9					.071					.220
I 10					.104					.084
I 11	10.8%	59.4%	29.8%	10.956	.002*	59.7%	17.1%	23.3%	19.031	.015*
I 12	9.4%	59.8%	30.8%	11.733	<.001*					.061
I 13					.106	82.0%	14.1%	3.9%	14.114	.029*
I 14					.126					.075
I 15	11.9%	56.8%	31.3%	14.410	<.001*	58.8%	17.1%	21.1%	18.017	.021*
I 16	9.9%	61.6%	28.5%	16.413	.037*					.071
I 17	12.9%	64.7%	22.4%	13.724	.001*	71.1%	15.1%	13.8%	14.996	<.001*
I 18					.058	71.4%	11.1%	17.5%	12.801	.002*
I 19					.113					.491
I 20	10.3%	66.9%	22.8%	16.934	<.001*	72.4%	13.8%	13.8%	10.519	.001*
I 21					.068	78.4%	9.9%	11.7%	16.440	.001*
I 22	21.6%	57.8%	20.6%	27.294	.009*	61.8%	15.7%	22.5%	12.500	.003*
I 23	22.5%	55.4%	21.1%	18.213	.036*	67.6%	10.8%	21.6%	15.087	.045*

*<.05; statistically significant, I; Item

planning and preparation of future experiences.²⁶ This study showed that nurses had difficulties practicing what they learned due to a heavy workload, an insufficient number of nurses, and uncertain progress of the disease. There are approximately 200.000 nurses in Türkiye, suggesting two nurses per every 1000 people in Türkiye.¹³ This rate indicates that nurses have been working with an extremely heavy workload during the pandemic. Moreover, this study revealed that the high workload and an insufficient number of nurses were obstacles to practicing what was learned. In the study, nurses also stated that they had difficulty in transferring the knowledge they learned to practice because they did not have enough equipment. Especially at the beginning of the pandemic, lack of equipment was an important problem. Studies have shown that lack of equipment causes stress in healthcare professionals and this situation negatively affects the learning process and decreases learning motivation.^{22,27-29}

It was determined that the age of the nurses affected their learning experiences related to COVID-19. Currently, three different generations work together in the working environments. Each generation has its own characteristics, values, beliefs, and ways of learning.³⁰ It is known that the

X generation is a self-sacrificing generation who tries to

solve their own problems and respects authority.³¹ When examined in terms of learning ways, the X generation wants to present the information directly and in the simplest way and to learn the information in the easiest and fastest way possible.³¹ Generation Y are individuals who are willing to learn, and innovative and they follow information mostly from internet resources as they are used to using computers.³¹ They prefer group projects that require more teamwork in their learning.³² Our study also supports this information and shows that Generation Y learns information about COVID-19 mostly from international scientific sources. On the other hand, study results showed that the nurses in the Generations X and Z prefer observation, trial and error. Individuals in the Z generation mostly prefer visual, affective, and active learning methods, they develop their professional skills through observation accompanied by practice. Individuals in Generation Z mostly prefer visual, affective, and active learning methods, and they develop their professional skills primarily through observation.

It was found that undergraduate nurses mostly learned information about COVID-19 from national and international scientific sources and Ministry of Health

guidelines and preferred to make observations. There are studies in the literature showing that nurses with a high level of learning obtain information from reliable websites.³²⁻³⁴ As the educational status increased, conscious efforts of learning increased, different learning sources were used, and international databases were utilized, which is an expected result and can be interpreted as an indicator of scientific attitude.

The workplace had an impact on learning attitudes. Nurses working in state hospitals gained information through institutional training, utilized international scientific references, and needed more information about the ways of infection and symptoms of the disease. Nurses working in state hospitals had more difficulties accessing up-to-date references due to a heavy workload, an insufficient number of nurses, fear of infection, accessing up-to-date and primary sources.

Limitations

The theoretical limitation of the study is the lack of sufficient sources in the literature. The methodological limitation of the study is the difficulties in accessing nurses due to the pandemic. The online collection of data limited the availability of sufficient information about the geographical region, hospital and patient density in which the participants worked. This resulted in the inability to fully analyze the effects of regional differences and hospital density within the scope of the study. The weak representation power of the sample size used in the study to represent the population limits the generalizability of the findings and the strength of data analysis. Another limitation is the absence of a valid and reliable scale for nurses' learning experiences.

It is necessary to determine the learning needs, learning experiences and learning styles of nurses for the planning of in-service training. The limited research on nurses' learning experiences highlights a need for further studies. It is thought that the findings obtained from this study, which examined the learning experiences of nurses regarding COVID-19, will guide the planning of educational activities. This study found that nurses primarily rely on national and international scientific sources, Ministry of Health guidelines, and observation methods to acquire information about COVID-19. Heavy workloads and staff shortages are key challenges that affects their learning processes. Nurses' educational backgrounds and workplaces also influence their learning experiences during the pandemic. While nurses actively follow relevant publications, professional constraints make it difficult to apply acquired knowledge in practice. Supporting nurses' access to information and improving their working

conditions are essential to addressing these issues. Up-to-date information sharing must be structured for easy access, and platforms for knowledge exchange at both national and international levels should be established. Nursing educators and administrators should offer training and psychological support to mitigate pandemic-related stress and boost motivation. Professional organizations must lead efforts to empower nurses during crises.

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Paternal and Maternal Holding-Cuddling for Procedural Pain in Healthy Term Neonates

Sağlıklı Term Bebeklerde Tıbbi İşlem Kaynaklı Akut Ağrı Yönetiminde Anne Kucağı ve Baba Kucağı

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ABSTRACT

Objective: Holding-cuddling helps reduce procedural pain. Studies have focused on the effect of the maternal holding-cuddling (MHC) method on heel prick pain in healthy-term neonates. However, there is limited study on the impact of paternal holding-cuddling (PHC) on procedural pain during heel pricks in neonates. This paper looked into the impact of MHC and PHC on heel prick pain and crying duration in healthy-term neonates.

Methods: This quasi-experimental study occurred in the obstetrics clinic of a university hospital in western Türkiye. The sample comprised 92 full-term neonates and their parents, divided into three groups: control (n=32), MHC (n=30), and PHC (n=30). The data were collected using a personal information form, a Neonatal Follow-up Form, and the Neonatal Infant Pain Scale (NIPS). The study received approval from an ethics committee.

Results: The MHC and PHC groups had a lower NIPS score than the control group during and after the procedure ($P<.05$). The MHC and PHC groups had a lower crying duration than the control group ($P<.05$). There was no difference in NIPS scores and crying duration between the MHC and PHC groups ($P>.05$).

Conclusion: Full-term infants held and cuddled by their parents tend to feel less pain and cry less during heel pricks. Nurses should use MHC and PHC to help infants have less pain during heel pricks.

Keywords: Infant, Nurse, Parent participation, Procedural pain

ÖZ

Amaç: Kucağa alma/ kucakta tutma pozisyonu, bebeklerde tıbbi işlemlerle ilişkili ağrıyı azaltmada etkili nonfarmakolojik yöntemlerden biridir. Çalışmalar sağlıklı term bebeklerde topuk kanı alma işlemi sırasında bebeğin anne kucağında tutulmasının etkisine odaklanmıştır. Bebeğin babasının kucağında olmasının tıbbi işlem kaynaklı ağrıya etkisini inceleyen sınırlı sayıda çalışma bulunmaktadır. Bu çalışma, sağlıklı term bebeklerde topuk kanı alma işlemi sırasında anne kucağı ve baba kucağında olma yöntemlerinin ağrı düzeyi ve ağlama süresi üzerine etkisini incelemek amacıyla yapıldı.

Yöntemler: Bu yarı deneysel çalışma, Türkiye'nin batısında bir üniversite hastanesinin kadın doğum kliniğinde yapıldı. Örneklemi, araştırma grubu seçim kriterlerini taşıyan 92 term bebek ve ebeveyni oluşturdu. Katılımcılar üç gruba atandı: Kontrol (n=32), anne kucağı (n=30) ve baba kucağı (n=30). Veriler Tanıtıcı Bilgi Formu, Yenidoğan Ağrı Ölçeği (NIPS) ve Yenidoğan Bebek İzlem Formu ile toplandı. Araştırmanın yapılabilmesi için etik onay, resmi izin ve ailelerden yazılı onam alındı.

Bulgular: İşlem sırasında ve sonrasında anne kucağı ve baba kucağı gruplarının NIPS puanları kontrol grubundan istatistiksel olarak daha düşüktü ($P<.05$). Anne kucağı ve baba kucağı gruplarının ağlama süresi kontrol grubundan istatistiksel olarak daha düşüktü ($P<.05$). Anne kucağı ve baba kucağı gruplarının NIPS puanları ve ağlama süreleri birbirine benzerdi ($P>.05$).

Sonuç: Topuk kanı alma işlemi sırasında anne veya babalarının kucağında tutulan term bebekler kontrol grubuna göre daha az ağrı yaşadı ve daha az ağladı. Hemşireler topuk kanı alma ile ilişkili ağrı yönetiminde anne kucağı ve baba kucağı yöntemlerini kullanabilirler.

Anahtar Kelimeler: Ebeveyn katılımı, Hemşire, Term bebek, Tıbbi işlem ağrısı

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INTRODUCTION

Newborns undergo many painful procedures.¹ Acute procedural pain causes behavioral stress and unstable hemodynamics. These problems negatively affect adaptation, growth, development, and parent-infant interaction.²⁻⁶ The heel prick is a painful procedure used for newborn screening tests and is more painful than other blood collection procedures.⁷

Healthcare professionals should prioritize pain management during heel pricks for two reasons. Firstly, they have an ethical obligation to minimize the pain neonates experience during medical procedures. Secondly, it has been reported that repeated painful exposures can have harmful consequences.² The American Academy of Pediatrics (2016) drew up a report on preventing and managing procedural pain in newborns and made some recommendations for neonatal healthcare institutions. First, healthcare institutions should develop a pain prevention program to minimize the number of painful procedures on neonates. Second, healthcare institutions should formulate a pain assessment and management plan to help healthcare professionals assess pain routinely and choose pharmacological and non-pharmacological treatments to help patients avoid the pain associated with minor procedures.² The International Guide to Pediatric Anesthesia (Good Practice in Postoperative and Procedural Pain) recommends both pharmacological and non-pharmacological methods for preventing and effectively managing acute procedural pain in children.⁸ However, pharmacological methods for pain management in neonates can have side effects.⁹ On the other hand, non-pharmacological methods are easy to use, affordable, time-effective, and have no side effects.¹⁰

Some popular non-pharmacological methods including environmental control interventions for pain management during heel pricks in healthy term neonates are swaddling,^{11,12} skin-to-skin contact,^{13,14} holding,^{11,12} heel warming,^{15,16} positioning methods (facilitated tucking, rocking, etc.),^{13,17} therapeutic touch.¹⁸ Healthcare professionals avoid non-pharmacological methods that are expensive, difficult to apply, and time-consuming.¹⁰

Holding-cuddling helps reduce procedural pain. Holding-cuddling is an easy to use, practical, non-invasive and inexpensive practice. Holding-cuddling is a non-pharmacological method that uses tactile stimulation to reduce pain by soothing the baby with rhythmic and repetitive movements. neonates held or cuddled by their mothers are likely to have less pain^{4,12,19,20} and cry less²⁰⁻²² during heel pricks. The maternal holding and cuddling (MHC) and paternal holding and cuddling (PHC) methods

provide multisensory inputs that enhance analgesic effects. These multisensory methods can reduce the infant's signs of pain during minor painful procedures and shorten the crying time.^{4,23} Bembich et al.²⁴ reported that MHC is related to bilateral somatosensory and right inferior frontal cortex activation during heel pricks in term neonates. This type of analgesia may be mediated by multisensory stimulation linked to the mother-infant attachment.²⁴ Therefore, this study focused on MHC and PHC to prevent procedural pain in neonates during heel pricks.

Many researchers have focused on the impact of MHC on procedural pain during heel pricks in neonates. Studies indicate that the MHC method helps neonates have less pain and cry less during heel pricks.^{4,11,12,19,20,24,25} However, no studies were found on the impact of the PHC method on procedural pain during heel pricks in neonates. In many societies, mothers are primary caregivers for sociocultural reasons. Healthcare professionals generally leave out fathers during painful medical procedures on neonates. Fathers feel powerless, inadequate, and stressed because they cannot participate in the care of their babies who undergo medical procedures.^{26,27} However, fathers who are there for their babies during medical procedures develop a bond with them and experience less anxiety and inadequacy. In addition, when mothers are not available due to medical emergencies, fatigue, or cesarean sections (C-sections), fathers can be a valuable alternative to help their babies go through minor painful procedures.^{28,29}

AIM

Therefore, this study investigated whether the MHC and PCH methods helped neonates feel less pain and cry during heel pricks.

Research hypothesis

We hypothesized the following:

- H1 The MHC and PHC groups would have lower mean NIPS scores during and after the procedure than the control group.
- H2 The MHC and PHC groups would have lower mean crying duration than the control group.

METHODS

Place of study

This quasi-experimental study was conducted between February 4 and August 20, 2016, in the obstetrics clinic of a baby-friendly certificated university hospital in western Türkiye. The clinic has 15 physicians, nine nurses, and 22 inpatient beds.

Participants

The study population included all women who gave birth in

the clinic and their babies. Power analysis (G*Power) was performed to determine the sampling adequacy. The results revealed a power of 0.89 at a significance level of 0.05, a confidence interval of 0.98, and an effect size of 0.37 ($n_1=32$, $Mean_1=6.93$; $n_2=30$, $Mean_2=5.76$; $n_3=30$, $Mean_3=5.83$; $SD=1.45$). The initial sample consisted of 105 neonates. Thirteen participants were excluded due to the exclusion criteria [($n=8$) sleeping during the procedure, ($n=2$) receiving analgesics up to 24 hours before the procedure, ($n=3$) smoking parents]. The sample consisted of 92 neonates divided into three groups: control ($n=32$), MHC ($n=30$), and PHC ($n=30$). The group assignment was determined using the closed envelope method. Therefore, data were collected first from the MHC group, followed by the PHC and control groups. Figure 1 shows the flow diagram for recruitment.

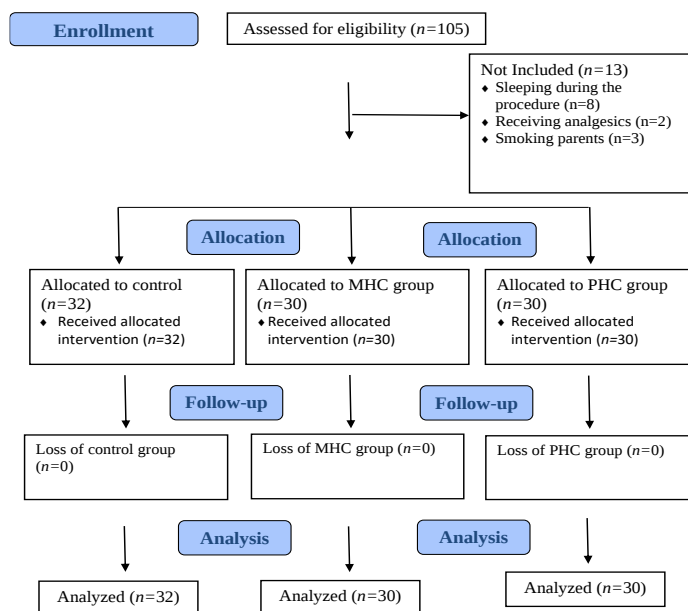


Figure 1. CONSORT Diagram of The Study.

The inclusion criteria were as follows: (1) healthy term neonates, (2) birth weight between 2500 and 4000 g, (3) 38-42 gestational week, (4) postnatal age of 48-72 hours, (5) a 5-minute APGAR score of ≥ 8 , (6) having had no experience of any painful interventions other than vitamin K and hepatitis B vaccine at birth, (7) fed between 30 and 60 min before the procedure, (8) undergoing heel prick only once, (9) blood collection for the Guthrie test, (10) willing to hold their babies during the procedure. The exclusion criteria were as follows: (1) sleeping during the procedure, (2) receiving analgesics up to 24 hours before the procedure, and (3) smoking parents.

Data collection tools

The data were collected using a personal information form, a Neonatal Follow-up Form, and the Neonatal Infant Pain Scale (NIPS).

Personal Information Form: The personal information form was developed by the researchers.^{20,30,31} The form consisted of items on neonatal gender, birth age, birth weight, APGAR score, delivery and feeding type, number of children, etc. After the form was prepared, opinions were received from three specialist nurses whose field of study was newborns, and the form was finalized in line with their opinions.

Neonatal Follow-Up Form: The neonatal follow-up form was developed by the researchers. The form was used to record the procedure time, crying time, etc.

Video Recorder: The procedures were recorded using a Samsung Galaxy Note 5 N920 (Operating System: Android 5.1.1 (Lollipop) Processor: Quad-core 1.5 GHz Cortex-A53 & Quad-core 2.1 GHz Cortex-A57).

Neonatal Infant Pain Scale (NIPS): The scale is a six-item measure developed by Lawrence et al.³² and adapted into Turkish by Akdovan.³³ The instrument assesses procedural pain in neonates. It is a behavioral scale assessing five behavioral indicators (facial expression, crying, arms, legs, and state of alertness) and one physiological indicator (breathing patterns). Five items (facial expression, breathing pattern, arms, legs, and state of alertness) are scored as 0 (Good) or 1 (Bad), while one item (crying) is scored as 0 (Good), 1, or 2 (Bad). The total scale score ranges from 0 to 7, with higher scores indicating more pain.³³ The original scale has a Cronbach's alpha of 0.92 to 0.97.³² At the same time, the Turkish version has a Cronbach's alpha of 0.92 to 0.97.³³ In the present study, the scale had a Cronbach's alpha of 0.81 and 0.94 during and after the procedure, respectively.

Procedure

The researcher conducted face-to-face interviews with participants to determine their socio-demographic characteristics. The interviews were held in the procedure room. The data collection took around five minutes. The researcher informed all parents about the research purpose and procedure and received written consent from all participants.

Blood samples were collected (procedure) in the intervention room of the clinic between 9:00 am and 11:00 am. The clinic nurse, with at least five years of experience, collected all the samples in accordance with the routine clinical procedures. The nurse had no conflict of interest. A

pediatrician decided on the procedure. Swaddling is used for pain management in neonates whose heel blood is collected during the clinical procedure. Therefore, all neonates were swaddled. All neonates were monitored for two minutes before the procedure, during the procedure, and three minutes after the procedure.

Routine procedure: Each neonate was fed 30-60 minutes before the procedure. Its diaper was changed just before the procedure. The same procedure was applied to all neonates. The nurse swaddled the baby with her own blanket with the right leg out. The nurse wiped the outer lateral side of the baby's right heel with 70% alcohol. She waited 30 seconds for the alcohol to dry. She used the same type of automatic lancet to prick the heel. She dropped a few drops of blood on a filter paper for the Guthrie screening test. She then covered the injection point with a dry cotton pad. The same environmental conditions (room temperature, light, and noise control) were provided for all neonates.

The control group participants (n=32) underwent the procedure according to routine clinical practice. Either parent brought the baby into the procedure room and laid it on the procedure table in the supine position. The nurse collected the blood sample. The parent was present in the room and communicated with the baby only verbally during the procedure. The parent picked up the baby after the procedure.

Each MHC group participant (n=30) was brought to the procedure room by its mother. The mother sat in a comfortable chair with back support. She held her baby close to her chest, with the baby's head in a crossed position so that it could see its mother. The same nurse collected the blood sample. The mother communicated with the baby verbally and made eye contact with it to calm it down during the procedure. She was holding the baby both during and after the procedure.

Each PHC group participant (n=30) was brought to the procedure room by its father. The father sat in a comfortable chair with back support. He held his baby close to his chest, with the baby's head in a crossed position so that it could see its father. The same nurse collected the blood sample. The father communicated with the baby verbally and made eye contact with it to calm it down during the procedure. He was holding the baby both during and after the procedure.

The researcher recorded all neonates for two minutes before the procedure, during the procedure, and three minutes after the procedure. Their pain scores and crying times were determined using the videos. Two independent observers with PhDs in pediatric nursing filled out the NIPS simultaneously. Interrater reliability analysis was performed to determine whether there was consistency between their scores. The results showed an intraclass correlation coefficient of 0.94. The results were 0.96, 0.92, and 0.89 before, during, and after the procedure. These results indicated a robust agreement between the two observers.³⁴ The arithmetic mean of the two scores was calculated.

The total crying time during the procedure is between when the heel is pricked, and the injection site is covered with a cotton pad. The total crying time after the procedure is between when the procedure is completed and when the baby calms down. The researcher watched the videos to calculate the crying times.

Ethical considerations

The study received ethical approval from the ethics committee of the Faculty of Medicine of Çanakkale Onsekiz March University (Date: 03.02.2016 & No: 2016/13173). Informed consent was obtained from all participants. The study was registered at Clinical-Trials.gov (NCT06111534).

Statistical analysis

The data were analyzed using the SPSS (Chicago, IL, USA for Windows, version 18.0) at a significance level of 0.05. Means, standard deviation, medians, frequencies, rates, minimum and maximum values, and Cronbach's alpha values were used for data analysis. The one-way ANOVA test was used to compare the three groups for the normally distributed data. The Kruskal–Wallis test was used to compare the three groups for the non-normally distributed data. The Mann–Whitney U test was used to determine the source of significant differences. Pearson's Chi-square test was used to compare quantitative data. In addition, intraclass correlation coefficients were used to assess agreement between two independent observers.

RESULTS

The MHC, PHC, and control groups had a mean gestational age of 38.10 ± 7.07 , 39.03 ± 1.06 , and 39.12 ± 0.79 weeks, respectively. The groups were similar regarding gestational age, birth weight, height, 5-minute APGAR score, gender, delivery type, and the number of children ($P > .05$; Table 1).

Table 1. Descriptive Characteristics of Neonates and Parents (n = 92)

Characteristics	Control (n=32) Mean ± SD		MHC (n=30) Mean ± SD		PHC (n=30) Mean ± SD		F ^a	P
Gestational age (week)	39.12±0.79		38.10±7.07		39.03±1.06		.579	.563
Birth weight (g)	3272.18±373.92		3261.66±420.11		3198.33±406.30		.304	.739
Height (cm)	49.91±1.12		50.36±1.09		49.90±1.24		1.632	.201
5 th min APGAR scores	9.25±0.43		9.36±0.55		9.33±0.47		.464	.631
	n	%	n	%	n	%	χ ^{2b}	P
Gender								
Female	21	65.6	16	53.3	18	60.0	.974	.615
Male	11	34.4	14	46.7	12	40.0		
Delivery type								
Vaginal	21	65.6	17	56.7	18	60.0	.536	.765
Caesarean	11	34.4	13	43.3	12	40.0		
Number of children								
1	16	50.0	14	46.7	19	63.3	1.883	.390
2 and more	16	50.0	16	53.3	11	36.7		

^aANOVA test; ^bChi-square test; SD, standard deviation; MHC, maternal holding-cuddling; PHC, paternal holding-cuddling.

Table 2 shows the NIPS scores during and after the procedure. The MHC, PHC, and control groups had a mean procedural NIPS score of 5.76 ± 1.85 , 5.83 ± 1.48 , and 6.93 ± 0.24 , respectively. The MHC, PHC, and control groups had a mean post-procedural NIPS score of 1.46 ± 2.11 , 1.73 ± 2.28 , and 3.59 ± 3.34 , respectively. There was a significant

difference between the procedural and post-procedural NIPS scores ($P < .05$). The MHC group had a significantly lower mean NIPS score than the control group during and after the procedure ($P < .05$). The PHC group had a significantly lower mean NIPS score than the control group during and after the procedure ($P < .05$; Table 2).

Table 2. Comparison of NIPS Scores During and After Painful Procedure (n = 92)

NIPS	Control (n = 32)	MHC (n = 30)	PHC (n = 30)	^a P	^b P (Group 1-2)	^b P (Group 1-3)	^b P (Group 2-3)
During the procedure							
Min-Max (Median)	6-7 (7)	1-7 (6,5)	2-7 (6)				
Mean±SD	6.93±0.24	5.76±1.85	5.83±1.48	< .001	< .001	< .001	.745
After the procedure (2. min)							
Min-Max (Median)	0-7 (4)	0-7 (0)	0-6 (0)				
Mean±SD	3.59±3.34	1.46±2.11	1.73±2.28	.016	.015	.015	.655

SD, standard deviation; MHC, maternal holding-cuddling; PHC, paternal holding-cuddling; NIPS, Neonatal infant pain scale.

^aP, for Kruskal-Wallis Test; ^bP, for Mann-Whitney U Test

Table 3 compares the crying times during and after the procedure. The control group participants cried the most during (59.25 ± 1.72 sec) and after the procedure (41.66 ± 4.08 sec). The MHC group participants cried the least during the procedure (42.67 ± 7.99 sec). The PHC group participants cried the shortest after the procedure ($35.00 \pm$

6.45 sec). The groups had no significant difference in the post-procedural crying times ($P > .05$). However, there was a significant difference in the procedural crying times between the groups ($P < .05$). MHC and PHC group participants cried significantly less during the procedure than the control group participants (Table 3).

Table 3. Comparison of Crying Times During and After the Painful Procedure (n = 92)

Crying times (sec)	Control (n = 32)	MHC (n = 30)	PHC (n = 30)	^a P	^b P (Group 1-2)	^b P (Group 1-3)	^b P (Group 2-3)
During the procedure							
Min-Max (Median)	55-60 (60)	20-60 (45)	20-60 (52.5)				
Mean±SD	59.25±1.72	42.67±7.99	48.92±10.43	< .001	< .001	< .001	.003
After the procedure							
Min-Max (Median)	35-45 (42.5)	25-45 (40)	25-45 (35)				
Mean±SD	41.66±4.08	38.00±8.36	35.00±6.45	.177	.497	.55	.403

SD, standard deviation; MHC, maternal holding-cuddling; PHC, paternal holding-cuddling. ^aP, for Kruskal-Wallis Test; ^bP, for Mann-Whitney U Test.

DISCUSSION

The heel prick, or heel lancing, is a painful procedure. All our participants had high NIPS scores. While experts advise using pharmacological and non-pharmacological methods to prevent or lessen heel prick pain, pharmacological methods have side effects. Healthcare professionals also do not prefer non-pharmacological methods because they are costly and impractical procedures that take time.¹⁰ However, cost-effective and practical non-pharmacological methods are becoming popular for painful procedures. One of those methods is parental holding-cuddling. This study compared the effect of maternal holding-cuddling (MHC) and paternal holding-cuddling (PHC) methods on heel prick pain in neonates. Our results showed that both methods helped neonates show less pain ($P<.05$).

Maternal holding-cuddling is an effective non-pharmacologic method to relieve pain perception.²⁰ Our MHC group had lower pain scores and cried less during the procedure than the control group. Our MHC group had lower pain scores after the procedure than the control group. Karakoç and Türker²⁰ conducted a study with 120 newborns to investigate the effect of the MHC method and white noise on pain perceptions and crying during heel pricks. They found that the white noise group had lower pain scores and cried less during the procedure than the MHC group ($P<.05$). Obeidat and Shurique⁴ compared the efficacy of MHC with breastfeeding (Group 1) and MHC without breastfeeding (Group 2) in relieving painful responses during heel pricks in full-term neonates. They reported that Group 1 had lower pain scores than Group 2 ($P<.05$). Yilmaz and Inal¹³ looked into the effects of (1) swaddling, (2) swaddling and maternal holding, and (3) swaddling, maternal holding, and breastfeeding on heel prick pain levels in healthy term neonates and determined that the third method was more effective than the others ($P<.05$). However, the groups had no significant difference in total crying times. Bembich et al.¹⁹ conducted a study with 80 healthy term newborns divided into four groups: (1) oral glucose, (2) expressed breast milk, (3) maternal holding plus oral glucose, and (4) breastfeeding. They concluded that Group 3 had lower pain scores than Group 1 ($P<.05$). Inal et al.¹¹ investigated how effectively swaddling and maternal holding reduce pain levels during heel pricks in healthy-term newborns. They recruited 105 healthy neonates divided into swaddling (S), maternal holding (MH), and control (C) groups. They found that Group MH had a significantly lower mean procedural and post-procedural NIPS score than the control group ($P<.05$). However, they did not detect a difference in the total crying times between the groups.¹¹ Our results also showed that

the MHC group had a lower mean NIPS score than the control group, supporting the results of previous studies.

Healthcare professionals should encourage fathers to participate in medical procedures to make neonatal care more family-centered. Fathers can play as effective a role as mothers in painful minor medical procedures. For example, PHC can relieve the pain of neonates during heel pricks. Our PHC group had lower pain scores and cried less during the procedure than the control group. In addition, our PHC group had lower pain scores after the procedure than the control group. Earlier research has shown that the kangaroo father care method can help reduce neonates' pain levels during heel pricks.^{27,30,35}

The MHC and PHC group participants cried less during the procedure than the control group participants. However, there was no significant difference in the total crying times between the groups after the procedure. This is probably because the control group participants were calmed down by their parents as they were held by them after the procedure. However, the fact that there was no significant difference in the total crying times between the groups after the procedure indicates that the PHC method effectively reduces the pain and anxiety levels of neonates during heel pricks.

The results showed that the MHC and PHC groups had lower pain levels and cried less during the procedure than the control group. There was no difference in the NIPS scores between the MHC and PHC groups. We think this is the most important finding because fathers are more actively engaged in caring for their babies and are more interested in being there for them during medical procedures than they used to. Moreover, some mothers cannot be there for their babies due to postpartum medical complications. Therefore, fathers play a crucial role in relieving the pain levels of their babies undergoing medical procedures. Our results indicate that the PHC method is as effective as the MHC method in reducing the pain levels of neonates during heel pricks. This study focused on the effect of both MHC and PHC on pain levels and crying times of neonates undergoing heel pricks. The MHC group participants cried less than the PHC group participants during the procedure ($P<.05$). There was no difference in the total crying times between the two groups after the procedure ($P>.05$). Johnston et al.³⁰ examined the impact of maternal kangaroo care (MKC) and paternal kangaroo care (PKC) on the pain levels of preterm neonates during heel pricks. They scored pain at 30, 60, 90, and 120 seconds. They found that the MKC group had a lower mean pain score at 30 and 60 seconds than the PKC group. The two had no significant difference in the pain scores at 90

and 120 seconds.³⁰ Our result suggests mothers are better at soothing and calming their babies than fathers. This is probably because mothers have a unique relationship with their babies and are more experienced in calming them down than fathers.

Limitations

The study has three limitations. First, due to the nature of the trial, researcher blinding could not be performed. The researcher knew to which group the neonates would be assigned. Two observers assessed the primary variable to reduce investigator bias. Additionally, statistical blinding was performed. Second, the intervention could not be blinded. The two observers who watched the video recordings saw the whole body of the newborn to observe the behavioral responses to the painful intervention. Thus, they could see which intervention (MHC, PHC, control) was given to the neonate. Third, the control group underwent no active intervention to detect the effectiveness of the MHC and PHC methods during the procedure. The control group only received routine swaddling.

Full-term neonates held and cuddled by their parents (MHC and PHC) have less procedural pain and cry less than those who are not. MHC and PHC methods effectively reduce the procedural pain of neonates during heel pricks. However, full-term neonates held and cuddled by their mothers cry less during heel pricks than those held and cuddled by their fathers. Our results indicate that the PHC method is as effective as the MHC method in managing procedural pain in neonates undergoing heel pricks. Healthcare professionals can safely use the MHC and PHC methods to relieve the pain levels of neonates undergoing heel pricks. Our results showed that the MHC and PHC methods helped neonates to have fewer signs of pain and cry less during the procedure. Our results indicate that the PHC method is as effective as the MHC method in managing procedural pain. More research is needed to explore the impact of these methods on painful procedures.

Etik Komite Onayı: Etik kurul onayı Çanakkale Onsekiz Mart Üniversitesi Yerel Etik Kurulu'ndan (Tarih: 03.02.2016, Sayı: 2016-13173) alınmıştır.

Hasta Onamı: Bu çalışmaya katılan tüm katılımcılardan yazılı bilgilendirilmiş onam alınmıştır.

Hakem Değerlendirmesi: Dış bağımsız.

Yazar Katkıları: Fikir- FYK, AAÖ, SK, SA; Tasarım- FYK, AAÖ, SK, SA, NA,HA; Denetleme- FYK, AAÖ, SK, SA; Kaynaklar- FYK, AAÖ, SK, SA, HA; Veri Toplanması ve/veya İşlemesi- FYK, AAÖ, SK, SA, NA; Analiz ve/veya Yorum- FYK, AAÖ, SK, SA, NA,HA; Literatür Taraması- FYK, AAÖ, SK, SA, NA,HA; Yazıyı Yazan- FYK, AAÖ, SK, SA, HA; Eleştirel İnceleme- FYK, AAÖ, SK, SA, NA,HA.

Teşekkür: Çalışmaya katılan tüm yenidoğanlara ve ailelerine teşekkür ederiz.

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The Status of Nurses Working in Surgical Units in Delivering Patient Education on Venous Thromboembolism

Cerrahi Birimlerde Çalışan Hemşirelerin Venöz Tromboembolizm ile İlgili Hasta Eğitimi Verme Durumu

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ABSTRACT

Objective: This study was planned to examine the status of education delivered by nurses working in surgical units regarding venous thromboembolism (VTE).

Methods: This descriptive cross-sectional study was conducted between May 2024 and June 2024. The study participants consisted of 126 nurses working in the surgical units of a city hospital in Türkiye. Data were collected using the "Patient Education Practice Form" developed by the researcher. Descriptive statistics (number, percentage, mean, standard deviation, median values) were used for data analysis.

Results: When examining the nurses' education practices, 19.8% stated that they always delivered patient education on mobilization, ankle exercises, and correct leg positioning while sitting; 19.1% on signs and symptoms of VTE; 19.0% on lifestyle changes; 18.3% on anticoagulants; 18.2% on laboratory tests in pharmacological prophylaxis; 17.5% on situations requiring emergency admission and patient safety; 16.7% on hydration; and 15.9% on elevating the legs and using compression stockings.

The issues nurses faced in delivering patient education included difficult working conditions and insufficient nursing staff (86.5%), lack of knowledge about VTE (54.8%), absence of guidelines on VTE and patient education in the clinic (53.2%), considering patient education as the physician's responsibility (48.4%), insufficient presentation and teaching skills (47.6%), lack of prioritization of patient education activities in the institution, lack of teaching materials (45.2%), and low health literacy of patients (32.5%).

Conclusion: Increasing nurses' knowledge and awareness through education on delivering patient education regarding VTE and addressing the perceived barriers to patient education by surgical nurses are essential for ensuring effective patient instruction.

Keywords: Surgical nursing, patient education, venous thromboembolism

ÖZ

Amaç: Bu çalışma cerrahi birimlerde çalışan hemşirelerin venöz tromboembolizm (VTE) ile ilgili eğitim verme durumlarını incelemek amacı ile planlandı.

Yöntemler: Bu tanımlayıcı kesitsel çalışma Mayıs 2024- Haziran 2024 tarihleri arasında gerçekleştirildi. Çalışmanın katılımcıları Türkiye' deki bir şehir hastanesinin cerrahi birimlerinde çalışan 126 hemşireden oluşmaktaydı. Veriler araştırmacı tarafından geliştirilen "Hasta Eğitimi Uygulama Formu" kullanılarak toplandı. Verilerin analizinde tanımlayıcı istatistikler (sayı, yüzde, ortalama, standart sapma, medyan değerler) kullanıldı.

Bulgular: Hemşirelerin eğitim verme durumları incelendiğinde; %19,8'i mobilizasyon, ayak bileği egzersizleri ve otururken doğru bacak pozisyonu; %19,1'i VTE belirti bulguları; %19,0'ı yaşam tarzı değişiklikleri; %18,3'ü antikoagülanlar, %18,2'si farmakolojik profilaksiste laboratuvar testleri; %17,5'i acile başvurulması gereken durumlar ve hasta güvenliği; %16,7'si hidrasyon, %15,9'u bacakların yükseltilmesi ve kompresyon çorabı kullanımı ile ilgili her zaman hasta eğitimi verdiklerini belirtmişlerdir. Hemşirelerin hastalara eğitim verme konusunda yaşadıkları sorunlar arasında zor çalışma koşulları ve hemşire sayısının yetersizliği (%86,5), VTE ile ilgili bilgi eksiklikleri (%54,8), klinikte VTE ve hasta öğretileri ile ilgili kılavuzların bulunmaması (%53,2), hasta eğitimlerini hekimin görevi olarak düşünme (%48,4), sunum ve öğretim becerilerinin yetersiz olması (%47,6), kurumda hasta eğitim faaliyetlerine öncelik verilmemesi, öğretim materyali eksikliği (%45,2) ve hastaların sağlık okuryazarlığının düşük olması (%32,5) vardı.

Sonuç: Hemşirelerin VTE ile ilgili hastalara eğitim vermeleri konusunda bilgi ve farkındalıklarının eğitimlerle artırılması ve cerrahi hemşireleri tarafından hasta eğitimi konusunda algılanan engellerin ortadan kaldırılması, etkili hasta öğretimi sağlanabilmesi için önemlidir.

Anahtar Kelimeler: Cerrahi hemşireliği, hasta eğitimi, venöz tromboembolizm

INTRODUCTION

In surgical processes, one of the main complications known as the "Silent Killer" is Venous Thromboembolism (VTE), which includes Deep Vein Thrombosis and Pulmonary Embolism.¹ The reported incidence of VTE varies between 48/100,000 to 160/100,000, causing significant morbidity and mortality among surgical patients in Türkiye and the world.¹⁻³ Estimates suggest 60,000–100,000 Americans die from thromboembolic conditions and, the incidence rate of DVT in Asia was between 3% and 28%.^{1,2} In a cross-sectional study conducted in Türkiye, the incidence of VTE was 4.6% among 1,000 patients diagnosed with cancer.⁴ Moreover, VTE extends hospital stays and increases healthcare costs, making it a vascular issue of considerable concern.¹⁻³ However, despite its potentially life-threatening nature, VTE is preventable.⁵ Various organizations such as the Association of Perioperative Registered Nurses (AORN) and the National Institute for Health and Care Excellence (NICE) have developed guidelines to prevent VTE and reduce associated mortality.^{3,5-9} In these guidelines it is recommended that patient education is one of the strategies for VTE management.

Patient education is a process of learning and teaching aimed at fostering behavior changes to maintain, enhance, and sustain health.¹⁰ Planned patient education during the perioperative process is crucial for developing effective coping strategies for existing health issues, reducing potential complications, preventing repeated hospital admissions, and improving quality of life.¹¹ Studies have shown that patient education leads to positive patient outcomes such as adaptation to illness, utilization of effective coping methods, maintenance of daily life activities, and reduction in mortality and morbidity both before and after surgery.¹¹⁻¹³ A study involving approximately 9,000 patients indicated that nurse-delivered VTE education led to a 5.3% increase in compliance with prophylaxis.¹⁴ In another study, a patient education program implemented by nurses, which included VTE management, resulted in a lower incidence of VTE symptoms in postoperative patients and fewer emergency department visits for VTE diagnosis.¹¹

On the other hand, in the constantly changing healthcare system, patients are discharged shortly after surgery. This shift places more responsibility on patients and their families to manage care, handle new health conditions, and ensure the treatment process progresses positively. Adequate patient education is crucial for them to meet these obligations.¹⁵ Nurses play a pivotal role in providing effective patient education tailored to meet the needs, enabling patients to cope with existing health issues,

achieve disease adaptation, actively participate in healthcare decisions, and develop health-promoting and enhancing behavioral changes.¹⁶ Research has demonstrated that nurse-delivered patient education is effective in preventing many complications including VTE.¹¹⁻¹³ In this context, both guidelines and studies emphasize the critical role of nurses in managing VTE through patient education. However, the literature reveals insufficient evidence regarding the status of nurses in providing VTE-related education to patients.^{17,18} It is crucial to determine the status of nurses in delivering education on VTE, the perceived barriers to delivering effective education, and to plan appropriate strategies to address these barriers.¹⁶

AIM

This study was designed to examine the status of delivering patient education on venous thromboembolism among nurses working in surgical units.

Research Questions

1. What is the status of nurses in surgical units in delivering patient education on venous thromboembolism?
2. What barriers do nurses in surgical units face in delivering patient education?

METHODS

Design and Sample

This descriptive cross-sectional study was conducted with nurses working in the surgical units of a city hospital in Türkiye (surgical services, surgical intensive care units, operating rooms) between May 2024 and June 2024. The study population consisted of 249 nurses working in the surgical units of the city hospital, and the sample consisted of 126 nurses who agreed to participate in the study and had worked in the surgical units for at least three months during the specified dates. The participation rate of nurses in the study was 50.6%. There was no protocol or in-service training program related to patient education for VTE at the clinics where the research was conducted.

Data Collection Tools

Patient Education Implementation Form (PEIF): The form, created based on guidelines from universally recognized organizations such as The European Society for Vascular Surgery (ESVS), The Association of periOperative Registered Nurses (AORN), and the National Institute for Health and Care Excellence (NICE), consists of two sections. The first section includes 13 questions related to descriptive characteristics such as age, gender, work unit, and previous education on VTE and patient education. The

second section contains four Likert-type questions that explore whether nurses deliver patient education on VTE, the subjects covered in patient education, and the barriers encountered in patient education. The form consists of a total of 17 questions. The form was presented to six nursing faculty experts with experience and studies related to VTE and patient education for suitability. The necessary adjustments were made based on their feedback to finalize the form. The study found a Cronbach's alpha value of 0.81, indicating that the questions demonstrated acceptable internal consistency and reliability.

Pre-Application

A pre-application was conducted with 10 nurses who met the research criteria. No issues were identified during the implementation of the form, so no changes were made to the form. The nurses who participated in the pre-application were not included in the study.

Application

Data was collected by the researcher through face-to-face interviews using the PEIF. Participants were delivered with necessary explanations by the researcher before the application, and written and verbal consent was obtained. It took approximately 10-15 minutes to complete the form.

Data Analysis

The data was analyzed using the IBM SPSS Statistics Standard Concurrent User V 26 (IBM Corp., Armonk, New York, USA) statistical package program. Descriptive statistics such as unit number (n), percentage (%), mean $\pm$ standard deviation, and median (minimum-maximum) values were used.

Ethics Approval

Before the study, necessary ethical approvals were obtained from the Yozgat Provincial Health Directorate Ethics Committee (Approval Number: E-16180230-772.02-243579660 Date: 05\17\2024). The study was conducted according to the Declaration of Helsinki.

RESULTS

The mean age of the nurses in the study was 27.84 ± 3.03 years, with the majority (63.5%) being female. The majority of participants were university graduates (84.9%), and more than half (65.1%) were married. 27.7% of nurses reported previous training related to VTE, while 14.3% indicated receiving education on patient education (Table 1).

Table 1. Distribution of descriptive characteristics of nurses (n=126)

Descriptive characteristics	
Age	
Mean $\pm$ SD, Median (min-max)	27.84 $\pm$ 3.03, 28 (22-36)
Gender	
	n (%)
Female	80 (63.5)
Male	46 (36.5)
Educational status	
Health vocational high school	19 (15.1)
University	107 (84.9)
Work unit	
Surgical services	61 (48.4)
Surgical intensive care unit	35 (27.8)
Operating room	30 (23.8)
Marital status	
Single	44 (34.9)
Married	82 (65.1)
Work year	
Mean $\pm$ SD, Median (min-max)	6.14 $\pm$ 2.54, 6.0 (1.0-14.0)
Previous education status	
Venous thromboembolism	35 (27.7)
Patient education	18 (14.3)
Summary statistics are presented as mean $\pm$ SD (standard deviation) for numerical data and as number (percentage) for categorical data.	

It was found that nurses consistently delivered patient education at the following rates: mobilization and ankle exercises (19.8%), importance of hydration (16.7%), leg elevation (15.9%), choosing loose clothing for legs (19.8%), proper leg positioning while sitting (19.8%), signs and symptoms of VTE (19.1%), situations requiring emergency admission (17.5%), side effects of anticoagulants (18.3%), importance of laboratory tests in pharmacological prophylaxis (18.2%), importance, correct usage, and complications associated with compression stockings (15.9%), adapting to lifestyle changes (19.0%), and home patient safety measures after discharge (17.5%) (Table 2).

Participants identified several problems in providing patient education, including long working hours, difficult working conditions, insufficient nurse numbers (86.5%), lack of knowledge about VTE (54.8%), lack of guidelines related to VTE and patient education in the clinic (53.2%), belief that patient education is the responsibility of physicians (48.4%), inadequate presentation and teaching skills (47.6%), lack of prioritization of patient education activities and lack of teaching materials (45.2%), and low health literacy among patients (32.5%) (Table 3).

Table 2. Distribution of education subjects on VTE delivered by nurses (n = 126)

Education subjects	Never n(%)	Sometimes n(%)	Always n(%)
The importance of mobilization and ankle exercises	56(44.5)	45(35.7)	25(19.8)
The importance of hydration	59(46.8)	46(36.5)	21(16.7)
Leg elevation	63(50.0)	43(34.1)	20(15.9)
Choosing loose clothing for legs	58(46.1)	43(34.1)	25(19.8)
Proper leg positioning while sitting	53(42.1)	48(38.1)	25(19.8)
Signs and symptoms of VTE	57(45.2)	45(35.7)	24(19.1)
Situations requiring emergency admission	53(42.1)	51(40.4)	22(17.5)
Who to contact when experiencing issues with post-surgical VTE protocol adherence	69(54.8)	36(28.6)	21(16.6)
Side effects of anticoagulants	72(57.1)	31(24.6)	23(18.3)
The importance of adhering to laboratory test schedules for patients on pharmacological VTE prophylaxis	69(54.8)	34(27.0)	23(18.2)
The importance, correct usage, and complications associated with compression stockings (such as skin discoloration, numbness, itching)	63(50.0)	43(34.1)	20(15.9)
Lifestyle changes (nutrition, smoking, weight control, exercise, etc.)	42(33.4)	60(47.6)	24(19.0)
Home patient safety measures after discharge (preventing falls, avoiding injuries, daily activities, proper medication use, etc.)	59(46.8)	45(35.7)	22(17.5)

Summary statistics are presented as numbers (percentage) for categorical data

Table 3. Distribution of problems faced by nurses in providing patient education (n=126)

Problem	Problem n(%)	No problem n(%)
Long working hours, difficult working conditions, insufficient number of nurses	109(86.5)	17(13.5)
Lack of knowledge about VTE	69(54.8)	57(45.2)
Inadequate presentation and teaching skills	60(47.6)	66(52.4)
The belief that patient education is the doctor's responsibility	61(48.4)	65(51.6)
Patients' unwillingness to receive education	49(38.9)	77(61.1)
Patients' lack of motivation to apply given information	41(32.5)	85(67.5)
Negative attitude of the patient's family towards education	51(40.5)	75(59.5)
Patients' health issues hindering education	57(45.2)	69(54.8)
Patients' difficulty in adapting to lifestyle changes	61(48.4)	65(51.6)
Lack of professional nurses in patient education	60(47.6)	66(52.4)
Lack of prioritization of patient education activities in the institution	57(45.2)	69(54.8)
Lack of teaching materials	57(45.2)	69(54.8)
Lack of a suitable educational environment	60(47.6)	66(52.4)
Lack of guidelines related to VTE and patient education in clinics	67(53.2)	59(46.8)
Communication problems with patients and the multidisciplinary team	60(47.6)	66(52.4)
Patients' low health literacy	41(32.5)	85(67.5)

Summary statistics are provided as numbers (percentage) for categorical data

DISCUSSION

The current study was conducted to investigate the status of nurses working in surgical units in delivering patient education on VTE. Our findings indicate that nurses' responses regarding delivering patient education on VTE in surgical units were low rate. In the study, it was observed that the number of nurses who responded "always" for patient education subjects specified according to current guidelines was quite low (ranging from 15.9% to 19.08%). In a study conducted in South Korea, similar findings were

reported regarding the inadequacy of nurses' providing patient education;¹⁹ it was noted that only 7.7% of nurses consistently delivered education on the effects of anticoagulants to patients, 3.5% on VTE symptoms, and 2.9% on lifestyle changes (such as smoking, diet, weight loss). In the study of Yohannes et al.¹⁸, nurses reported that they sometimes or never delivered information to patients about the importance of anticoagulants and fluid intake, injury prevention, and lifestyle changes. In another study by Al-Mugheed and Bayraktar²⁰, 56.4% of nurses did not deliver education on anticoagulants, 73.9% on injury

prevention, 66.1% on adequate hydration, and 67.9% on the proper use of compression stockings. In this context, it can be said that our study results are consistent with the literature. However, ensuring adherence to VTE treatment in hospitalized patients and preventing VTE significantly depends on patient education.²¹ Nurses not delivering comprehensive and effective patient education can lead to negative patient outcomes. Indeed, a recent study in the literature reported that a significant portion of patients did not comply with prophylaxis in the postoperative period, were unaware of the side effects of prophylactic medications, and that 30% experienced a lack of knowledge about VTE.²² Considering the increasing incidence of VTE among surgical patients, preventing VTE is crucial for positively influencing patient outcomes and reducing prolonged hospital stays.²³ In this regard, both guidelines and studies emphasize that comprehensive and effective patient education delivered by nurses is a vital strategy in the management of VTE.¹⁷

In this study, it is considered that the inadequate responses regarding patient education delivered by nurses may be attributed to the problems they encounter in delivering such education. The majority of nurses (86.5%) reported that long working hours, difficult working conditions, and insufficient number of nurses were important problems in providing patient education. Similarly, in the studies by Bazezew et al.²⁴ and Fereidouni et al.²⁵ in the literature, it is also stated that the insufficiency of the number of nurses, the heavy workload of nurses, and long working hours are barriers to providing effective education. According to the Organisation for Economic Co-operation and Development (OECD)²⁶, in Türkiye, the number of nurses per 1000 population is 2.4, which is below the OECD average. This situation is an objective indicator of the insufficiency of nursing staff and the high workload. On the other hand, surgical units are unstable environments due to surgical interventions defined as controlled traumas. These procedures temporarily make patients of all ages dependent and involve constantly changing hemodynamic conditions. Furthermore, these factors, combined with insufficient nursing staff, place surgical nurses in face of numerous complex problems, exacerbate workplace conditions, and compromise the quality of patient care and consequently, surgical patient safety.²⁷ It is therefore believed in the study that nurses may not have sufficient time for patient education due to these reasons. Under national health policies, implementing necessary regulations to improve nurses' working conditions and adjusting nurse-to-patient ratios will enhance the quality of patient care, ensure nurses deliver education to patients at

the desired level, improve individuals' health outcomes, and positively impact healthcare costs.²⁸

In the study, one of the other crucial issues that nurses encounter in patient education was the lack of knowledge about VTE (54.8%). According to AORN⁷, with effective patient education, patients will be able to better understand ways to prevent VTE even after discharge and actively participate in their own care. Effective patient education can only be delivered by healthcare professionals who have accurate knowledge about VTE. Unfortunately, studies show that nurses' knowledge and practices related to VTE are insufficient.^{18-20,23} In this study, the fact that more than half of the nurses reported a lack of knowledge about VTE suggests that the quality of their undergraduate and in-service education should be evaluated and improved, the retention of knowledge should be ensured using appropriate teaching methods and techniques. In the study, only 27.7% of the nurses stated that they had previously received VTE training. Additionally, the absence of a VTE-related subject in the existing in-service training programs in clinics may contribute to the inadequacy of patient education. In this context, it is crucial to improve nurses' knowledge and practices related to VTE management through courses, in-service training programs, conferences, etc., to ensure effective patient education.

In the study, more than half of the nurses indicated that the absence of clinical guidelines in hospitals posed a barrier to providing patient education. Al-Mugheed and Bayraktar¹⁷, Yohannes et al.¹⁸ and Bazezew et al.²⁴ similarly indicated that there is a lack of guidelines related to VTE management and patient education in clinics. Clinical guidelines are primary sources to encourage nurses to implement evidence-based practices effectively. They ensure standardization in practices and care, emphasize preventing complications, and are recommended for improving healthcare professionals' practices related to VTE prevention.²⁹ Recently, the National Institute for Health and Care Excellence (NICE)⁵ identified VTE prevention protocols in clinics as one of the top 10 patient safety practices. Establishing institutional protocols that standardize the management of VTE was recommended in a systematic review.¹⁷ In one study, it was highlighted that implementing a nurse protocol in clinics significantly improved nurses' knowledge and practices while substantially reducing VTE risks for patients.³⁰ In this context, the creation of protocols for VTE patient education is considered crucial for standardizing patient education and for effectively managing VTE. Indeed, a recent large-scale study suggested that a VTE education protocol could

prevent over 134,000 VTE cases within five years.³¹

In the study, nearly half of the nurses mentioned the lack of prioritization of patient education activities in the institution (45.2%), the absence of suitable educational environments (47.6%) and teaching materials for training (45.2%), and the lack of professional nurses in patient education (47.6%) are obstacles to providing effective patient education. In several earlier studies, it was similarly stated that a lack of managerial interest, insufficient professional nurses in patient education, the presence of unsuitable environments for education, and inadequate educational materials pose barriers to delivering patient education.^{24,32,33} As known, using audiovisual aids in education appeals to multiple senses, facilitating perception and learning, while enhancing the retention of information, thus increasing the effectiveness of education. Moreover, a conducive physical environment (such as adequate space, good lighting, and quiet surroundings) positively impacts the quality of teaching and enhances learners' motivation for learning. On the other hand, nurses need to approach patient education professionally by identifying educational needs, creating an appropriate education plan, providing effective teaching with effective methods and materials, and, evaluating the effectiveness of the education.¹⁰ In this context, it is believed that institutions should prioritize patient education in their policies, provide appropriate environments and materials for education, and offer in-service training to nurses on patient education. These measures could significantly enhance patient education practices.

In the study, only a small number of nurses (14.3%) reported having received prior education on patient education. Additionally, most nurses identified inadequate presentation skills as another problem they face in providing patient education. If nurses are well-trained and empowered to improve patient outcomes, it implies they have significant roles and responsibilities in preventing VTE. Among these roles, assessing patients' awareness of VTE and providing guiding information for VTE prevention are crucial. Recently, a randomized controlled study conducted by Özbaş et al.¹¹ investigated the effects of planned patient education, including VTE management, in surgical patients; It was observed in the study that the group receiving education showed a lower incidence of VTE symptoms (such as redness, numbness, and swelling), and fewer patients were admitted to the emergency department with a diagnosis of VTE. Therefore, enhancing nurses' knowledge of patient education is considered essential for achieving the desired performance in patient education and fostering positive patient outcomes.

In the study, nurses identified low health literacy among patients as a barrier to effective patient education. Health literacy is defined as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to be able to make informed health decisions, and, health literacy is crucial for patients to comprehend their surgical conditions. Unfortunately, the literature indicates that health literacy is significantly low both in Türkiye and globally.^{12,34} Patient education developed in accordance with the patients' level of health literacy can improve not only their knowledge but also clinical outcomes such as postoperative complications and quality of life. Indeed, Özbaş and Karadağ¹² found that education tailored to the level of health literacy significantly reduced postoperative problems. At this point, patient education materials that use simple language and short sentences, avoid medical jargon, and enhance readability with explanatory diagrams and images can improve compliance with instructions, thereby ensuring effective patient education.^{12,34}

Another notable finding in the study was that nearly half of the nurses perceived patient education as the responsibility of physicians. Although the literature on this subject is limited, a previous study similarly reported that nurses considered delivering patient education to be the responsibility of physicians.²⁴ However, in Türkiye, the roles of nurses in patient education are legally emphasized by the Turkish Nursing Regulation.³⁵ It is believed that nurses' lack of knowledge about the information deficiencies regarding nurses' roles and responsibilities in patient education can influence their attitudes, behaviors, and practices toward patient education. It is important to implement comprehensive in-service training and raise awareness to improve nurses' knowledge and perceptions about their roles and responsibilities in patient education, ensuring that they give the necessary importance to patient education. Surgical patients are more susceptible to VTE compared to medical patients, and VTE is a significant cause of sudden deaths in hospitals.²⁰ Providing patients with personalized, consistent, and comprehensive education on VTE by nurses can potentially reduce morbidity and mortality rates, improve quality of life, and decrease hospital readmissions, thus alleviating financial burdens as well.^{11,12,17}

Study limitations

The study is limited to the answers given to the data collection forms by nurses working in the surgical units of a city hospital. It cannot be generalized to all nurses.

Study results showed that nurses' responses regarding providing patient education on VTE in surgical units were at

a low rate. To ensure effective patient education on VTE, it is crucial to increase nurses' knowledge and awareness of VTE-related patient education through training, develop evidence-based clinical guidelines to standardize patient education practices, and address other barriers perceived by surgical nurses (such as long working hours, difficult working conditions, insufficient number of nurses, institutional neglect of patient education, and lack of educational materials and appropriate environments).

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Hasta Onamı: Çalışmaya başlamadan önce hemşirelere araştırma hakkında gerekli bilgilendirmeler yapıldı ve onamları alınmıştır.

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Cerrahi Hemşireliğinde Teknoloji Kullanımı; Sistematisik Derleme

Technology Use in Surgical Nursing; Systematic Review

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ÖZ

Amaç: Bu derleme, 2012-2022 yılları arasında “Teknoloji ve Cerrahi Hemşireliği” konusuna ilişkin yayınlanmış çalışmaların sistematisik olarak değerlendirilmesi amacıyla yapılmıştır.

Yöntemler: Konuya ilişkin “Cerrahi hemşireliği”, “Teknoloji”, “Teknoloji ve hemşirelik bakımı”, “İnovasyon” anahtar kelimeleri kullanılarak 9 veri tabanı Türkçe ve İngilizce taranmıştır. Konuyla ilgili 2012 Ocak–2022 Eylül tarihleri arasında yayınlanmış 14.672 çalışma incelenmiş ve 21 yayın çalışmaya dahil edilmiştir.

Bulgular: Araştırma kapsamına alınan çalışmalar incelendiğinde, cerrahi hemşireliği alanında teknolojiyi kullanmanın perioperatif hemşirelik alanında başarıyı arttırdığı, elektronik hasta değerlendirme programlarını kullanırken hastalarla daha çok zaman geçirildiği, elektronik hasta devirlerinin hasta ve veri transfer sürecini kolaylaştırdığı, hasta bakım kalitesini arttırdığı, ortak bakım alanı oluşturduğu, hasta güvenliğine katkı sağladığı ve hemşirelik uygulamalarını geliştirdiği sonucuna varılmaktadır.

Sonuç: Cerrahi hemşireliğinde teknoloji kullanımına yönelik daha fazla kanıt temelli araştırma yapılmasının önemli olacağı düşünülmektedir.

Anahtar Kelimeler: Cerrahi hemşireliği, teknoloji, teknoloji ve hemşirelik bakımı, İnovasyon.

ABSTRACT

Objective: This review, regarding "Technology and Surgical Nursing" between 2012-2022 the aim of this study was to systematically evaluate published studies.

Methods: Nine databases were searched in Turkish and English using the keywords "surgical nursing", "technology", "technology and nursing care", "innovation". A total of 14,672 studies published on the subject between January 2012 and September 2022 were examined and 21 publications were included in the study.

Results: When the studies included in the research are examined, it is seen that using technology in the field of surgical nursing increases the success in the field of perioperative nursing, more time is spent with the patients while using electronic patient assessment programs, electronic patient transfers facilitate the patient and data transfer process, increase the quality of patient care, create a common care area, contributes to patient safety and improves nursing practices.

Conclusion: It is thought that it will be important to conduct more evidence-based research on the use of technology in surgical nursing.

Keywords: Surgical nursing, technology, technology and nursing care, Innovation.

GİRİŞ

Cerrahi hemşireliği, cerrahi girişim öncesinde/ sırasında/ sonrasında bireyin fizyolojik, psikolojik ve sosyo-kültürel gereksinimlerini karşılayan, bireye özgü hasta bakımını uygulayan, iyilik halinin tekrar kazanılması ve yükseltilmesini sağlayan, hemşirelik işlevlerinin biyolojik, fizyolojik ve davranış bilimi ile şekillendirilen özel bir hemşirelik dalı olarak tanımlanmıştır.¹ Cerrahi hemşiresinin hasta kabulünden başlayıp taburculuğa kadar olan süreçte hastanın güvenliğini ve rahatını sağlamak, destekleyici ve güven verici bir ortam hazırlamak, hastanın sağlıklı ve kaliteli bir yaşama erişmesini sağlamak, hastaya bireyselleştirilmiş bakım sunmak gibi önemli sorumlulukları vardır. Tüm alanları etkileyen ve insanlık için büyük önem arz eden bilim ve teknolojiye yaşanan hızlı ve sürekli gelişmeler, teknolojik yöntemlerin kullanılmasını ayrıcalıktan ziyade zorunluluk haline getirmektedir. Sağlık hizmetlerinde teknoloji ilk olarak hemşirelerin işlerini kolaylaştırmak ve verdikleri bakımın kalitesini artırmak amacıyla kullanılmıştır.² İlerleyen dönemlerde, hastaların günlük yaşam aktivitelerinin desteklemesi, hastaların eğitimi, hasta takibi ve sağlık hizmetlerine daha kolay erişim sağlamak için kullanılmaya başlanmıştır.³

Günümüzde yoğun bilgi ve teknolojik gelişmeleri takip eden sağlık hizmetlerinde, hemşirelik ve hemşirelik bakımı uygulamalarında yeni teknolojilerin olumlu etkileri görülmektedir.⁴ Krick'in⁵ dijital teknoloji ve hemşirelik bakımının etkinliği ve verimlilik üzerine yapılmış 715 yayını değerlendirdiği çalışmada; etkililik çalışmalarının en fazla bilgi teknolojileri, robotlar ve sensörler için gerçekleştirildiğini, verimlilik çalışmalarının nadir olarak yapıldığı sonucuna ulaşılmıştır. Literatür taraması sonucunda yüksek kanıt değeri taşıyan çalışma tasarımlarının sıklıkla bilgi teknolojileri, robotlar ve dijital öğrenme-uygulama alanlarında yapıldığı görülmektedir. Bu durum, hemşirelerin sağıkta bilişim teknolojilerinin kullanımına yönelik bilgi, tutum, farkındalık ve hazır oluşluk düzeyleri, teknolojinin hemşirelik ve hasta bakımı üzerindeki etkisini belirleyen araştırmaların üzerine yoğunlaşılması gerektiğini ortaya koymaktadır.^{6,7} Bu çalışma ile cerrahi hemşireliğinde teknoloji kullanımının etkilerini belirleyerek, ilgili mevcut durumu ortaya koyarak geliştirilecek yeni çalışmalara katkı sağlanabilir.

AMAÇ

Bu sistematik derleme ile cerrahi hemşireliği alanında yapılmış teknoloji ile ilgili çalışmaların sonuçlarına dayanarak, teknoloji kullanımının sağlık hizmetleri sunumundaki etkinliğinin değerlendirilmesi amaçlanmaktadır.

Araştırma soruları

- Cerrahi hemşireliğinde kullanılan teknolojiler nelerdir?
- Cerrahi hemşireliğinde kullanılan teknolojilerin sağlık hizmetleri sunumundaki etkileri nelerdir?

YÖNTEMLER

Araştırmanın Tasarımı

Sistematik derleme olarak hazırlanan bu çalışmada, sistematik derleme protokolünün oluşturulmasında ve makalenin yazılmasında PRISMA Bildirimi'nden (PRISMA Statement-Sistematik Derleme ya da Meta-Analiz Araştırma Raporunun Yazımında Bulunması Gereken Maddelerle İlgili Kontrol Listesi) faydalanılmıştır. Çalışma protokolünün, PROSPERO'ya kaydı yapılmıştır (Kayıt no: 03.07.2023/CRD42023415157).

Tarama Stratejisi

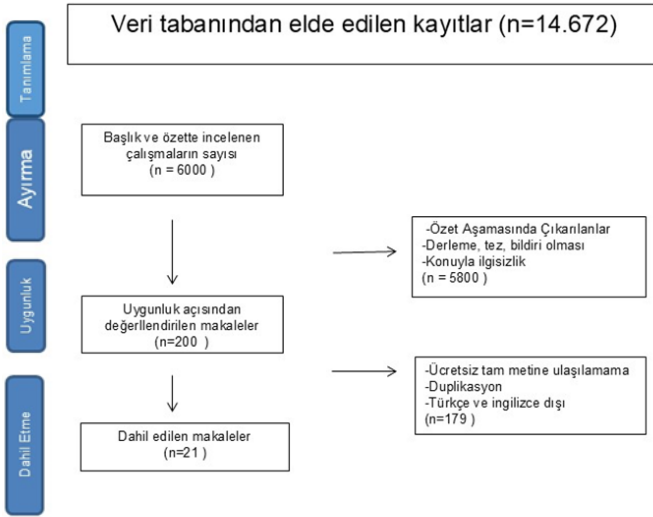
Konuyla ilgili "Cerrahi hemşireliği", "Teknoloji", "Teknoloji ve hemşirelik bakımı", "İnovasyon" anahtar kelimeleri kullanılarak TR dizin, Pubmed, Elsevier, EBSCO, Springer, Scopus, Wiley Online Library, Ovid, Web of Science veri tabanları Türkçe ve İngilizce taranmıştır. Tarama sonucunda 2012 Ocak–2022 Eylül tarihleri arasında yayınlanmış 14.672 çalışma incelenmiştir. Belirlenen çalışmalardan özet, editöre mektup, derleme, tez çalışması ve bildiriler kapsam dışı bırakılmıştır. Cerrahi hemşireliğinde teknolojinin kullanımı kapsamında planlanan ve tam metnine ulaşılan 21 yayın çalışmaya dahil edilmiş ve sonuçları açısından değerlendirilmiştir. Dahil edilen 21 makale deneysel, randomize kontrollü çalışma, karma yöntem, nitel yöntem, tanımlayıcı ve gözlemsel araştırma tipi tasarımıdadır. Araştırmacılar konuyla ilgili başlık ve özetleri incelemiş, çalışmaların yayınlanma yılları, örneklemeleri, kullanılan ölçüm araçları bağımsız olarak diğer araştırmacı tarafından gözden geçirilmiştir. Sistematik derlemede taranan çalışmaların sayısı, kriterleri sağlayan ve derlemeye alınan, dışlanan araştırmalar ve dışlanma nedenleriyle birlikte PRISMA akış şemasında belirtilmiştir (Şekil 1).

Araştırmaya Dahil Etme Kriterleri

Araştırmaya dahil edilme kriterleri; cerrahi hemşireliğinde teknolojinin kullanımı kapsamında planlanmış olması, 2012 Ocak–2022 Eylül tarihleri arasında yayınlanmış olması, araştırma makalesi olması ve tam metnine ulaşılabilmesi olarak belirlenmiştir.

Araştırmaya Dahil Edilmeme Kriterleri

Özet, derleme, editöre mektup, tez çalışmaları ve kongre bildirileri çalışmaya alınmamıştır.



Şekil 1. PRISMA Akış Şeması

Veri Çekilmesi (Çıkarılması)

Araştırma verilerini elde etmek için araştırmacılar tarafından geliştirilen veri çıkarma aracı kullanılmıştır. Bu veri çıkarma aracı ile çalışmanın yazarları ve yayın yılı, araştırma tasarımı, araştırmanın amacı, örneklem büyüklüğü, kullanılan ölçüm araçları, çalışmaların temel sonuçları değerlendirilmiştir. Veri çıkarımı, olası yanlışlık riskini azaltmak için iki araştırmacı tarafından bağımsız olarak gerçekleştirilmiş ve daha sonra her iki araştırmacının da bulunduğu bir oturumda kontrol edilerek tek bir metne dönüştürülmüştür (Tablo 1). Gelişen görüş ayrılıkları tartışma yoluyla ve gerektiğinde üçüncü araştırmacının desteğiyle çözülmüştür.

Çalışmaların Metodolojik Kalitesinin Değerlendirilmesi

Bu sistematik derlemeye dahil edilen çalışmaların kalite değerlendirmesi iki araştırmacı tarafından bağımsız olarak gerçekleştirilmiş ve üçüncü araştırmacının da katıldığı bir oturumda kontrol edilerek ortak bir metin haline getirilmiştir. Oluşan görüş ayrılıkları bu oturumda tartışılarak giderilmiştir. Değerlendirmeye alınan araştırmaların metodolojik kalitesinin incelenmesi için Joanna Briggs Institute (JBI) tarafından düzenlenen randomize kontrollü, yarı deneysel, nitel ve kesitsel çalışmalar için Kritik Değerlendirme Kontrol Listelerinden yararlanılmıştır. Bu kontrol listelerinde yarı deneysel çalışmalar 9, randomize kontrollü 13, kesitsel çalışmalar 8, nitel çalışmalar 10 soruluk bir değerlendirme ile puanlanmaktadır. Sorular “Evet, Hayır, Belirsiz ve Uygulanmaz” şeklinde cevaplanarak form doldurulmuştur. Araştırmaya alınan çalışmaların metodolojik kalite düzeyi, maddelerin %50’sinden azı “evet” olarak değerlendirildi ise

“vasat”, maddelerin %51-80’i arasında “evet” olarak değerlendirildi ise “orta kalite” ve maddelerin %80’inden fazlası “evet” olarak değerlendirildi ise “iyi kalite” olarak kabul edilmektedir. Bu sistematik derlemeye sentez edilen çalışmaların kalite değerlendirme düzeyi 8 çalışmada iyi^{10,14,17,18,23-25,27}, 11 çalışmada orta^{8,9,11-13,15,16,20-22,26}, 2 çalışmada ise vasat^{19,28} şeklinde bulunmuştur.

BULGULAR

Bu araştırmada veri tabanlarının taraması sonucunda toplam 14.672 çalışmaya ulaşılmıştır. Planlanan tarama stratejisi ile başlık ve özetle seçim yapılarak ve tekrarlar çıkarılarak 21 çalışma, tam metin olarak incelenmiştir. Araştırma kapsamına alınan 21 çalışma incelenerek aşağıdaki temalar belirlenmiştir.

Elektronik veri sistemleri kullanımının cerrahi hemşireliğine etkisi

Elektronik veri sistemleri kişisel sağlık kayıtları, test sonuçları, anamnez, muayene, doktor istemleri, hemşirelik bakım planı ve epikriz benzeri tıbbi bilgilerin haricinde hastaya ilişkin kullanılan malzemeler gibi tıbbi olmayan bilgileri de içermektedir. Elektronik veri sistemleri sağlık bakımının sonuçlarının değerlendirilebilmesi için gereken klinik bilgilere elektronik olarak erişilmesini sağlamaktadır. Böylece performansa dayalı bakım kalitesinin değerlendirilmesini kolaylaştırmakta ve sürekli kalite iyileştirme çalışmalarına büyük katkılar sunmaktadır. Elektronik veri sistemleri kullanmanın cerrahi hemşireliğine etkisi 3 çalışmada ele alınmıştır.

Sun ve ark.⁸ çalışmasında, hastaların devir teslimi sırasında elektronik veri sistemleri kullanmanın klinisyen memnuniyetini %69,4’ten %79,3’e yükselttiği, iletişim bütünlüğü algısının ise %67,2’den %81,6’ya yükseldiği belirtilmiştir. Yontz ve arkadaşlarının⁹ çalışmasında, hemşireler elektronik veri sistemleri kullanmanın faydalı olduğunu, iş yükünü artırmadığı belirtilmiştir. Fakat hemşireler bu sistemleri kullanmanın belgeleri iyileştirmede ve hemşirelik işlerini ortadan kaldırmayacağını düşündüklerini ifade etmişlerdir. Moore ve Fisher¹⁰ cerrahi hemşirelerinin mevcut klinik uygulamalarında sağlık bilgi teknolojisini nasıl kullandığını keşfetmeyi ve bu teknolojinin hemşirelerin klinik karar vermeleri üzerindeki etkisini incelemeyi amaçladığı nitel çalışmada 8 hemşirenin görüşüne başvurulmuştur. Bu çalışmada, hemşirelik bakımının sağlanmasının artık tek bir sağlık profesyoneli tarafından değil, birbiriyle iş birliği içinde çalışan hemşireler ve teknolojiye oluşan bir ekip tarafından sağlanmasıyla yeni bir bakım ortaklığının ortaya çıktığı görülmüştür.

Tablo 1. Araştırma Kapsamına Alınan Çalışmalar

Yazar/ Yıl	Türü	Amaç	Örneklem	Ölçüm Aracı	Sonuçlar
Glanville ve ark. ¹⁸ /2021	Gözlemsel çalışma	Bu çalışma, cerrahi hemşirelerin klinik değerlendirmeye yaklaşımını belirlemek için bir e-öğrenme programının etkinliğini değerlendirmeyi amacıyla yapılmıştır.	74 hemşire	Veri toplama formu	E-Öğrenimin tamamlanmasının ardından, deney servisi hemşirelerinin klinik değerlendirme yapan hastalarıyla daha fazla zaman geçirdikleri gözlemlenmiştir. Her iki serviste de tüm hemşireler kapsamlı ABCDE (Havayolu, Solunum, Dolaşım, Bilinç, Ek etkiler) değerlendirmesi yapmadı ve ABCDE değerlendirmesinin sıralamasıyla ilişkili değişkenlik olduğu görülmüştür.
Sun ve ark. ⁸ /2018	Gözlemsel çalışma	Bu çalışma, kompleks cerrahi prosedürleri olan hastaların klinik transferleri (devir teslim) için elektronik sistemin etkinliğinin ve memnuniyetinin araştırılması amacıyla yapılmıştır.	20 hemşire	Anket	Elektronik sistemin kullanılmasıyla cerrahi devir teslim için geçen süre 10,5 dakikadan 5,4 dakikaya düşmüştür. Anket analizi, cerrahi devir teslimden klinisyen memnuniyetinin %69,4'ten %79,3'e yükseldiğini göstermiş, iletişim bütünlüğü algısı ise %67,2'den %81,6'ya yükselmiştir. Elektronik devir teslim sistemi, cerrahi hastaların devir tesliminde iletişimi iyileştirmiştir.
Kaya ve Karaman Özlü ¹¹ /2022	Randomize kontrollü çalışma	Bu çalışma, hastaların yanık pansuman sırasında sanal gerçeklik gözlüğü kullanmanın yaşadıkları ağrı, kaygı ve korku düzeylerine etkisini belirlemek amacıyla yapılmıştır.	65 yanık çocuk hasta	Tanımlayıcı Bilgi Formu Wong-Baker FACES Ağrı Derecelendirme Ölçeği Çocuk korku ölçeği Çocuklar için Durumluk-Sürekli Kaygı Envanteri (STAI-C) Başvuru kayıt formu Dikkat dağıtma yöntemi (sanal gerçeklik uygulaması)	Sanal gerçeklik, 7-12 yaş arası çocuklarda yanık pansumanın neden olduğu ağrı, korku ve kaygıyı azaltmada etkili bir yöntemdir. Yanık pansuman sırasında sanal gerçeklik gözlüğü kullanımının bazı fiziksel ve psikolojik parametreler üzerinde olumlu sonuçlar verdiği belirlenmiştir.
Sergeeva ve ark. ²² /2016	Gözlemsel +nitel çalışma	Bu çalışma, mobil cihazların tanıtılması ve kullanılmasının sağlık hizmeti uygulamaları üzerindeki istenen ve istenmeyen etkilerinin belirlenmesi amacıyla yapılmıştır.	180 hemşire	Anket Yarı yapılandırılmış görüşme	Mobil cihaz kullanmanın kolay bilgi erişimi, e-öğrenme ve işle ilgili iletişime (görüntüleme, teknisyenler ve cerrahlar ile fonksiyonel koordinasyonun iyileştirilmesi) olanak tanıdığı, ancak bazen dikkat dağıtıcı olarak algılandığı sonucuna ulaşılmıştır.
Unger ve ark. ¹² /2018	Gözlemsel çalışma	Bu çalışma, cihaz etkileşimlerinin neden olduğu bakteriyel kontaminasyon riskini ortadan kaldırmak için temassız etkileşim tekniklerinin etkinliğini belirlemek amacıyla yapılmıştır.	26 ameliyathane çalışanı	Van der Laan's technology acceptance questionnaire, NASA TLX anketi, NASA Raw-TLX'	Katılımcılar sistemi faydalı bulmuşlar ve memnun kalmışlardır. Ameliyathanede tıbbi cihazların artan sayısına rağmen, temassız etkileşimin steriliteyi koruduğu sonucuna ulaşılmıştır.
Teodoro ve ark. ²³ /2016	Randomize kontrollü çalışma	Bu çalışma, videoya kaydedilmiş hasta talimatından ve ambulasyon hedeflerine ilişkin günlük hasta hatırlatmalarından oluşan resmi bir ambulasyon programının hastanede yatan hastalarda etkinliğini belirlemek amacıyla yapılmıştır.	48 hasta	Pedometre	Klinisyenlerin uygulama rutinlerine kolayca dahil edilebilecek pragmatik bir ambulasyon programının, hastanede yatan hastalarda ambulasyona organize bir vurgu yapılmadan normal bakıma kıyasla ambulasyonu önemli ölçüde iyileştirdiği bulunmuştur. Hastanede yatışları sırasında ambulasyona tam olarak vurgu yapılmayan hastalar için, çalışma süresi boyunca ambulasyon mesafesinin azaldığı belirlenmiştir.

Tablo 1. Araştırma Kapsamına Alınan Çalışmalar (Devamı)

Yazar/ Yıl	Türü	Amaç	Örneklem	Ölçüm Aracı	Sonuçlar
Yontz ve ark. ^{9/} 2015	Tanımlayıcı çalışma	Bu çalışma, perioperatif hemşirelerin elektronik veri sistemi kullanımına yönelik tutumlarının belirlenmesi amacıyla yapılmıştır.	80 hemşire	Anket	Genel olarak, katılımcılar elektronik veri sisteminin faydalı olduğunu, iş yükünü artırmadığını ve hemşirelik işlerini ortadan kaldırmayacağını belirtmişlerdir.
Moore ve Fisher ^{10/} 2012	Nitel çalışma	Bu çalışma, cerrahi hemşirelerinin mevcut klinik uygulamalarında sağlık bilgi teknolojisi kullanma durumları ve sağlık hizmeti bilgi teknolojisinin hemşirelerin klinik karar vermeleri üzerindeki etkisinin incelenmesi amacıyla yapılmıştır.	8 hemşire	Odak grup görüşme	Hemşirelik bakım sürecinin, artık tek bir sağlık profesyoneli tarafından değil, belirlenen hedeflere ulaşmak için işbirliği içinde çalışan hemşireler ve teknolojiden oluşan bir ekip tarafından sağlanmasıyla yeni bir bakım ortaklığının daha etkili olacağı belirtilmiştir.
Hansen ^{24/} 2015	Deneyisel Randomize kontrollü çalışma	Bu çalışma, bir klinikte mobil teknolojiler aracılığıyla sunulan işitsel gevşeme tekniği, müzik müdahalesi, müzikli doğa video uygulaması ve müziksiz doğa video uygulaması kullanımının uygulanabilirliğini belirlemek amacıyla yapılmıştır.	105 Hasta	Sosyo-demografik anket Durumluk Kaygı Envanteri Sayısal Derecelendirme Ölçeği Genel Öz Yeterlik ölçeği	Gruplar arasında anksiyete, ağrı ve öz-yeterlik üzerine tüm müdahaleler için istatistiksel olarak anlamlı bulgular bulunmuştur. Müziksiz doğa video uygulaması ve müzikli doğa video uygulamasının yeni müdahalelerinin uygulanması, klinik uygulamaya ve tamamlayıcı tedavilerin literatürüne katkıda bulunduğu belirlenmiştir.
Martorella ve ark. ^{19/} 2014	Karma yöntem (nicel+nitel)	Bu çalışma, kalp cerrahisi sonrası ağrı yaşayan yetişkinlerin bakış açısından SOULAGE-TAVIE'nin (kendi kendine bakım için geliştirilmiş, bilgisayara özel ve Web tabanlı bir müdahale) kabul edilebilirliğini tanımlamak, kadın ve erkeklerin algılarını karşılaştırmak amacıyla yapılmıştır.	Nicel- 60 hasta Nitel- 20 hasta	Sosyodemografik veriler Postoperatif ağrı anketi Kısa Ağrı Envanteri TAP: Tedavi Kabul Edilebilirliği ve Tercihi Yarı yapılandırılmış görüşme	Kadınlar ve erkeklerin kabul edilebilirlik gerekçeleri farklılık gösterse de katılımcılar müdahaleyi içerik ve biçim açısından kabul edilebilir olarak belirtmişlerdir. Kadınlar verilen tavsiyenin önemine ve uygunluğuna dayalı olarak müdahaleye bağlı kalmaya istekliken, erkekler daha çok müdahalenin oluşum şekline odaklanmışlardır. Katılımcıların taburcu olduktan sonra SOULAGE-TAVIE deneyimi, bakımın sürekliliği açısından olumlu etkisini ortaya koymuştur.
Martorella G. ve ark. ^{20/} 2013	Pilot randomize kontrollü deneme	Bu çalışma, ameliyat sonrası ağrının kendi kendine yönetimini teşvik etmek için kalp ameliyatı geçiren yetişkinler için özel olarak hazırlanmış bir Web tabanlı hemşirelik müdahalesi (SOULAGE TAVIE) geliştirmek amacıyla yapılmıştır.	60 hasta	Sosyodemografik veriler Postoperatif ağrı anketi Kısa Ağrı Envanteri TAP: Tedavi Kabul Edilebilirliği ve Tercihi	Hastanın güçlendirilmesi, mevcut bakım sürecinde tamamlayıcı olmakla birlikte ağrının giderilmesine de katkıda bulunmuştur. Bilgi teknolojilerinin kullanımı, karmaşık bir bakım ortamında bakımı kişiselleştirmeyi ve sağlık eğitimine erişilebilirliği artırmaktadır.
Breteler ve ark. ^{13/} 2020	Tanımlayıcı çalışma	Bu çalışma, kablosuz sensörlerin yüksek riskli hastalarda olumsuz olayları tespit etme yeteneğini belirlemek amacıyla yapılmıştır.	31 hasta	Kablosuz yama sensörü Yatak tabanlı sistem Giyilebilen yaşam bulguları ölçme sensörü	Uzaktan hasta izleme sistemlerinin riskli cerrahi hastalarında hastanın kötüleşmesi durumunda hemşirelere erken uyarı oluşturma potansiyeline sahip olduğu ve bu şekilde hasta güvenliğini artırdığı belirlenmiştir.
Downey ve ark. ^{14/} 2018	Randomize, pilot çalışma	Bu çalışma, sürekli uzaktan yaşamsal belirtilerin izlenmesinin cerrahi hastaların takibindeki etkinliğini belirlemek amacıyla yapılmıştır.	226 hasta	Sensium Vitals yaması	Cerrahi servislerde uzaktan sürekli yaşamsal bulguların izlenmesi pratiktir ve hastalar için kabul edilebilirdir. Bu çalışma, genel cerrahi servis ortamında uzaktan sürekli izleme sisteminin uygulanmasının kabul edilebilirliğini göstermiştir.
Okgün ve ark. ^{28/} 2019	Tanımlayıcı çalışma	Bu çalışma, hemşirelerin robotik cerrahi konusundaki düşüncelerinin değerlendirilmesi amacıyla yapılmıştır.	286 hemşire	Araştırmacı tarafından hazırlanan soru formu	Hemşirelerin çoğunun robotik cerrahi konusunda farkındalığının yüksek olduğu halde sınırlı bilgiye sahip oldukları görülmüştür. Hemşireler bir operasyon geçirme durumunda robotik cerrahiye tercih edebileceklerini ifade etmişlerdir.

Tablo 1. Araştırma Kapsamına Alınan Çalışmalar (Devamı)

Yazar/ Yıl	Türü	Amaç	Örneklem	Ölçüm Aracı	Sonuçlar
Wang ve ark. ¹⁷ /2021	Deneysel çalışma	Bu çalışma, ameliyathanede basit sanal gerçeklik teknolojilerine dayalı hemşirelik müdahalesinin gastrointestinal cerrahi insizyon enfeksiyonunu önleme üzerindeki etkisinin belirlenmesi amacıyla yapılmıştır.	80 hasta	Depresyon Öz Değerlendirme Ölçeği, Anksiyete Öz Değerlendirme Ölçeği ve Öz Değerlendirme İntraoperatif Hemşirelik Müdahalesini Tanıma Ölçeği Anket	Ameliyathanede sanal gerçeklik ile hemşirelik müdahalesinin hastanın insizyon bölgesindeki enfeksiyon oranını azalttığı, insizyon bölgesinin mümkün olduğunca çabuk iyileşmesini desteklediği ve klinik tedavinin güvenliğini önemli ölçüde artırdığı belirlenmiştir.
Rantala ve ark. ²⁵ /2020	Nitel	Bu çalışma, pediatrik gündüz cerrahisi prosedüründe ebeveyn deneyimlerini tanımlamak ve bu prosedürleri kolaylaştırmak için dijital oyuna olan ihtiyacı belirlemek amacıyla yapılmıştır.	31 Hasta ebeveyni		Ebeveynlerin, çocuklarının günlük cerrahi bakımları için rehberliğe ve desteğe ihtiyacı vardır. Dijital bir oyun çözümü, iletişimi desteklemek ve gününbirlik ameliyatlara hakkında bilgi sağlamak için uygun bir araç olabilir. Aileler, destek/rehberlik sağlayan ve çocukları gününbirlik ameliyata hazırlayan dijital oyunun faydalı olacağını belirtmişlerdir.
Cook ve ark. ²⁶ / 2014	Gözlemsel çalışma	Bu çalışma, kalp ameliyatı geçiren yaşlı hastalara modüler eğitim ile mobil bilgi işlemi birleştiren yeni bir elektronik sağlık platformunun etkinliğinin değerlendirilmesi amacıyla yapılmıştır.	149 hasta	Mayo Clinic Health Connection yüklü İpad	Mobil bilgi işlemin bir içerik yönetim sistemiyle birleşimi, son derece kullanılabilir bir formatta eğitime olanak tanımış, ayrıca bu yaklaşım hastaların yeni sağlık hizmeti modellerinde bilinçli katılımcılar haline gelebileceği bir araç olarak belirlenmiştir.
Kang ve ark. ²⁷ /2016	Nitel çalışma	Bu çalışma, robotik cerrahi ile ilgilenen perioperatif hemşirelerin iş deneyimlerini araştırmak amacıyla yapılmıştır.	15 hemşire	Odak grup görüşmesi	Hemşireler robot sistemi arızasıyla ilgili acil durum olasılığında hasta güvenliği ile ilgili endişelerini belirtmişlerdir. Robotik cerrahiye ilgili hemşireler için daha fazla destek sunulmalı ve robotik cerrahide hemşireleri güçlendirmenin öncelikli olduğu sonucuna ulaşılmıştır.
Ingadottir ve ark. ²¹ / 2016	Nitel çalışma	Bu çalışma, cerrahi hastalarının postoperatif ağrı yönetimi hakkında bilgi edinmek için geleneksel ve yeni yöntemler hakkındaki algılarını karşılaştırmak amacıyla yapılmıştır.	13 hasta	Skeç Yarı yapılandırılmış görüşme	Hastalar en çok hemşire ile yüz yüze eğitimi tercih etmiş, bunu broşürler ve web siteleri takip ederken, dijital oyunlar en az tercih edilmiştir. Yeni eğitim yöntemlerini ameliyat sonrası bakıma başarıyla uygulamak için sağlık profesyonellerinin, hastaların öğrenmeye ilişkin algılarını etkileyen güven ve motivasyon gibi faktörlerin farkında olmaları gerekmektedir.
McGillion ve ark. ¹⁵ / 2021	Randomize kontrollü çalışma	Bu çalışma, covid-19 pandemisi sırasında elektif olmayan ameliyattan sonra taburcu edilen yetişkinler arasında Uzaktan otomatik izleme teknolojisi ile sanal bakımın standart bakıma karşı etkinliğinin değerlendirmesi amacıyla yapılmıştır.	905 hasta	Uzaktan otomatik izleme teknolojisi	Sanal bakım ve Uzaktan otomatik izleme, hastaların taburculuk sonrası yaşam süresini önemli ölçüde etkilememiştir. Ancak ilaç hatalarının saptanması ve düzeltilmesinde önemli bir artış ve ağrıda bir azalma belirlenmiştir. Sanal bakım ve uzaktan otomatik izleme sistemiyle, akut hastane bakımı, kısa süreli akut hastane bakımı ve acil servis ziyareti riskinin azaldığı görülmüştür.
Downey ve ark. ¹⁶ / 2019	Randomize kontrollü, paralel grup denemesi	Bu çalışma, yüksek komplikasyon riski taşıyan cerrahi sonrası hasta popülasyonunda giyilebilir uzaktan yaşamsal belirti monitörü ile kalp atış hızı, solunum hızı ve vücut sıcaklığının etkin ölçülmesi amacıyla yapılmıştır.	51 hasta	Sensium vitals izleme sistemi	Ölçülen her üç yaşamsal belirti için manuel ve giyilebilir uzaktan yaşamsal belirti yama ölçümleri arasındaki farklar kabul edilebilir sınırların dışında bulunmuştur.

Giyilebilir teknoloji kullanımının cerrahi hemşireliğine etkisi

Akıllı giyilebilir cihazlar akıllı bilezikler, giyilebilir sensörler, akıllı saatler ve akıllı gözlükler gibi günlük giyim ve aksesuarlar için kullanılabilen akıllı tasarımlardır.²⁹ Sanal gerçeklik teknolojisi ise bilgisayar teknolojisi ile en son yüksek teknolojiyi kullanarak, belirli bir aralıkta gerçek görsel, işitsel ve dokunsal sanal ortamlar oluşturan bir teknolojidir.^{29,30}

Giyilebilir teknoloji kullanımının cerrahi hemşireliğine etkisi incelenen 7 çalışma ile ele alınmıştır.

Kaya ve Karaman Özlü'nün¹¹ çalışmasında, 7-12 yaş arası hastalarda yanık yarası bakımı sırasında sanal gerçeklik gözlüğü kullanmanın ağrı, endişe, korku düzeylerini ve kalp atış hızlarını önemli ölçüde azalttığı bulunmuştur. Unger ve ark.¹² çalışmasında cihaz etkileşimlerinin neden olduğu bakteriyel kontaminasyon riskini ortadan kaldırmak için temassız etkileşim tekniklerinin etkinliğini belirlemeyi amaçlamıştır. Göz takibine dayalı destek sistemleri oluşturup, steriliteyi korurken ve elleri cerrahi aletleri manipüle etmek için serbest bırakırken etkileşimi mümkün kılan bir sistem geliştirmişlerdir. Çalışmanın sonucunda katılımcılar sistemi faydalı bulduklarını ifade etmiştir. Ameliyathanede tıbbi cihazların artan mevcudiyetine rağmen, temassız etkileşim ile sterilite korunarak hasta güvenliği sağlanmıştır. Breteler ve ark.'nın¹³ kablosuz sensörlerin yüksek riskli hastalarda olumsuz olayları tespit etme yeteneğini tanımlamak amacıyla gerçekleştirdiği çalışmasında, riskli cerrahi hastalarında uzaktan hasta izleme sistemlerinin hastanın kötüleşmesi durumunda erken uyarı oluşturma potansiyeline sahip olduğu ve bu şekilde hasta güvenliğini iyileştirmeye katkıda bulunduğu belirlenmiştir. Downey ve ark.¹⁴ giyilebilir Sensium Vitals yaması kullanarak, cerrahi hastalarının yaşamsal belirtilerini sürekli uzaktan izlemenin etkinliği araştırılmıştır. Bu çalışma, genel cerrahi servis ortamında uzaktan sürekli izleme sisteminin uygulanmasının etkinliğini ve kabul edilebilirliğini göstermiştir. McGillion ve ark.¹⁵ Covid-19 pandemisi sırasında elektif olmayan ameliyattan sonra taburcu edilen yetişkinlerde Uzaktan Otomatik İzleme teknolojisi kullanmanın evde hayatta kalma günlerine etkisini belirlemek amacıyla 905 hasta ile çok merkezli randomize kontrollü bir çalışma yapmıştır. Deney grubundaki katılımcılara tansiyon, kalp hızı, solunum hızı, oksijen doygunluğu, sıcaklık ve vücut ağırlığını ölçen bir tablet bilgisayar ve Uzaktan Otomatik İzleme teknolojisi verilmiştir. Otuz gün boyunca katılımcılar yaralarının günlük biyofiziksel ölçümlerini yapmış ve fotoğraflarını çekerek hemşirelerle sanal olarak etkileşimde bulunmuşlardır. Standart bakım grubundaki katılımcılar,

merkezin olağan bakımına göre hastane sonrası taburculuk yönetimi eğitimi almışlardır. Bu çalışmanın sonucunda Sanal bakım ve Uzaktan Otomatik İzleme, evde hayatta kalan günleri önemli ölçüde etkilememiş, ancak ilaç hatalarının saptanması ve düzeltilmesinde önemli bir artış ve ağızda bir azalma olduğu belirlenmiştir. Downey ve ark.'nın¹⁶ giyilebilir bir uzaktan yaşamsal belirti monitörünün, yüksek komplikasyon riski taşıyan cerrahi sonrası hasta popülasyonunda kalp atış hızını, solunum hızını ve sıcaklığı doğru bir şekilde ölçüp ölçemeyeceğini doğrulamak amacıyla yaptığı çalışmasında, ölçülen her üç yaşamsal belirti için manuel ve yaşamsal belirti yama ölçümleri arasındaki farklar kabul edilebilir sınırların dışında bulunmuştur. Sistemin sınırlamaları, daha iyi sinyal işleme yoluyla potansiyel olarak aşılabileceği öngörülmüştür. Wang ve ark.¹⁷ çalışmasında, ameliyathanede sanal gerçeklik ile hemşirelik müdahalesinin hastanın insizyon bölgesindeki enfeksiyon oranını azaltmaya, insizyon bölgesinin mümkün olduğunca çabuk iyileşmesini desteklemeye ve klinik tedavinin güvenliğini önemli ölçüde artırmaya yardımcı olabileceğini belirlemiştir.

Bilgisayar destekli eğitim ve öğrenme programlarının cerrahi hemşireliğine etkisi

Bilgisayar destekli eğitim ve öğrenme programlarının cerrahi hemşireliğine etkisini değerlendiren 4 çalışma ele alınmıştır.

Glanville ve ark.¹⁸ cerrahi hemşirelerinin klinik değerlendirmeye yaklaşımını belirlemede bir elektronik öğrenme programının etkinliğini değerlendirmek amacıyla yaptıkları çalışmada, E-öğrenimin tamamlanmasının ardından, deney servisi hemşirelerinin klinik değerlendirme yapan hastalarıyla daha fazla zaman geçirdiklerini gözlemlemişlerdir. Martorella ve ark.¹⁹ çalışmalarında bilgi teknolojilerinin kullanılmasının, karmaşık bir bakım ortamında bakımı kişiselleştirmeyi ve sağlık eğitimine erişilebilirliği artırdığı sonucuna ulaşmışlardır. Martorella ve ark.²⁰ kalp cerrahisi sonrası ağrı yaşayan yetişkinlerin bakış açısından SOULAGE-TAVIE uygulamasının kabul edilebilirliğini tanımlamak, kadın ve erkeklerin algılarını karşılaştırmak amacıyla karma yöntem bir çalışma gerçekleştirmiştir. Bu çalışma, akut bakım sürecinde ağrı inançlarını ve tutumlarını modüle etmek için bilgisayar uygulamasının ve ikna edici iletişimin kabul edilebilirliğini tanımlamaktadır. Kadınlar ve erkeklerin kabul edilebilirlik gerekçeleri farklılık gösterse de katılımcılar müdahaleyi içerik ve biçim açısından kabul edilebilir olarak belirtmişlerdir. Kadınlar verilen tavsiyenin önemine ve uygunluğuna dayalı olarak müdahaleye bağlı kalmaya istekliken, erkekler daha çok müdahalenin şekline ve

esnekliğine odaklanmışlardır. Ingadottir ve ark.²¹ çalışmasında, hastalar genel olarak hemşire ile yüz yüze eğitimi tercih ederken, bunu broşürler ve web siteleri takip etmiş, dijital oyunlar ise en az tercih edilmiştir.

Sağlık profesyonellerinin, ameliyat sonrası bakıma yönelik uygulanan yeni eğitim yöntemlerini nasıl kullanabileceğini hastalara öğretmesi, yeni yöntemlere yönelik hasta algısını etkileyen güven ve motivasyon gibi faktörler yönünden hastayı desteklemesi yeni eğitim yöntemlerinin başarılı olmasında yardımcı olacaktır.

Mobil teknoloji kullanımının cerrahi hemşireliğine etkisi

Mobil teknoloji kullanımının cerrahi hemşireliğine etkisini inceleyen 5 çalışma ele alınmıştır.

Sergeeva ve ark.'nın²² çalışmasında, mobil cihazların kolay bilgi erişimi, e-öğrenme ve işle ilgili iletişime (görüntüleme, teknisyenler ve cerrahlar ile çapraz fonksiyonel koordinasyonun iyileştirilmesi) olarak tanıdığını, ancak bazen dikkat dağıtıcı olarak algılandığı sonucuna ulaşılmıştır.

Teodoro ve ark.²³ çalışmasında hastanede yatan hastalar için video yöntemi ile hastaların ambulasyon eğitimine yönelik bir program hazırlanmıştır. Planlı ambulasyon programını (STEP-UP: kısa ambulasyon eğitici video kaseti, günlük ambulasyon hedeflerinin yayınlanması, ambulasyon hatırlatıcıları) olağan bakımla karşılaştırmak için bir ön test/son test randomize kontrollü deneme tasarımı kullanılmıştır. Klinisyenlerin uygulama rutinlerine kolayca dahil edilebilecek pragmatik bir ambulasyon programı, hastanede yatan hastalarda ambulasyonu önemli ölçüde iyileştirerek, hastaların hastanede yatışları sırasında STEP-UP'a geçmesine yardımcı olmuştur. Hansen²⁴ bir klinikte mobil teknolojiler aracılığıyla sunulan İşitsel Gevşeme Tekniği, Müzik Müdahalesi, Müzikli Doğa Video Uygulaması ve Müziksiz Doğa Video Uygulaması kullanımının uygulanabilirliğini belirlemek amacıyla bir çalışma gerçekleştirmiştir. Grup katılımcıları arasında, özellikle algılanan öz-yeterlik puanlarındaki artışta istatistiksel olarak anlamlı bulgulara ulaşılmıştır. Müzikli Doğa Video Uygulamasının 1. günden 5. güne kadar algılanan ağrı düzeylerinin azaltılmasında önem taşıdığını ve Müziksiz Doğa Video Uygulamasının başlangıçtan ameliyat sonrası döneme kadar öz yeterliliği artırmada önemli bir etkisi olduğu belirlenmiştir. İzlandaca sağlanan İşitsel Gevşeme Tekniği, katılımcıların ameliyat öncesi dönemden 10. gün takibine kadar öz yeterliliği üzerinde olumlu etkiler göstermiştir. Anksiyete öyküsü olan ve anti-anksiyete ilacı kullanan bireylerde anksiyeteyi azaltmak için teknolojik yöntemlerin kullanımının, tüm katılımcılar değerlendirildiğinde olumlu etkileri olduğu görülmüştür. Rantala ve ark.'nın²⁵ çalışmasında ebeveynlerin,

çocuklarının günlük cerrahi bakımları için rehberliğe ve desteğe ihtiyacı olduğunu belirlenmiştir. Aileler, çocukları

günübirlik ameliyata hazırlayan, destek ve rehberlik sağlayan bir dijital oyuna hazır olduklarını belirtmiştir. Cook ve ark.²⁶, mobil bilgi işlem ile içerik yönetim sistemini birleştiren yeni bir elektronik sağlık (e-sağlık) platformunun, kalp cerrahisi sonrası yaşlı hastalarda modüler eğitimin etkinliğini değerlendirmek için 149 hasta ile gözlemsel bir çalışma yapmıştır. Ortalama yaşı 68 olan 149 hastadan oluşan bir cerrahi popülasyon, 5,3 günlük hastanede yatış süresi boyunca verilen 6,295 eğitim modülünün 5,267'sini (%84) kullanmıştır. Çalışma sonucunda oluşturulan elektronik sağlık platformu kullanılabilir bir formatta dinamik, modüler, kişiselleştirilmiş bir eğitime olanak tanımış, ayrıca bu yaklaşım, hastaların yeni sağlık hizmeti modellerinde bilinçli katılımcılar haline gelebileceği bir araç olarak belirlenmiştir.

Robotik cerrahi ve cerrahi hemşireliğine etkisi

Robotik cerrahi ve cerrahi hemşireliğine etkisi ile ilgili 2 çalışma ele alınmıştır.

Kang ve ark.²⁷ robotik cerrahi ile ilgilenen perioperatif hemşirelerin iş deneyimlerini araştırmak amacıyla 15 hemşirenin görüşlerini alarak nitel bir çalışma gerçekleştirmiştir. Hemşireler arasında robot sistemi arızasıyla ilgili acil durum olasılığında hasta güvenliği ile alakalı ortak endişeler olduğu belirlenmiştir. Robotik cerrahiyle ilgili hemşireler için daha fazla destek sunulmalı, robotik cerrahide hemşireleri güçlendirmek bir öncelik olmalıdır. Okgün ve ark.'nın²⁸ yaptığı çalışmada, hemşirelerin çoğu robotik cerrahi konusunda farkındalıklarının yüksek olduğunu fakat sınırlı bilgi sahibi olduklarını belirtirken, kendilerinin cerrahi bir operasyon geçirme olasılığı oluştuğunda robotik cerrahiye tercih edebileceklerini ifade etmişlerdir.

Sağlık teknolojisinde gelişme gösteren yöntemlerden biri olan robotik cerrahi konusunda hemşirelerin bilgilerinin güncellenmesi, hemşirelerin konuyla ilgili görüşlerinin ve etkileyen faktörlerin belirlenmesi için daha geniş kapsamlı çalışmaların yapılması önerilebilir.

İncelenen çalışmalarda cerrahi hemşireliği alanında kullanılan teknolojilerin elektronik veri sistemleri, giyilebilir teknolojiler, bilgisayar destekli programlar, mobil teknolojiler ve robotik cerrahi olduğu görülmektedir. Gelişen teknolojilerin cerrahi hasta bakımına entegre edilmesiyle, hemşirelerin yenilikçi bakım teknikleri geliştirmeleri, klinik hasta bakımında bağımsız kararlar alabilmeleri ve hastalara verilen etkin bir bakımla sağlık hizmetleri sunumunda kalitenin artırılması hedeflenmektedir.

TARTIŞMA

Sistematiik derlemeye dahil edilen alıřmalar bütüncül olarak deęerlendirildięinde; 19 alıřmanın yurtdıřında yapıldıęı, 2 alıřmanın Türkiye’de yapıldıęı görülmüřtür. İncelenen deneysel ve yarı-deneysel arařtırmalarda örneklem büyüklüęünün 48-905 arasında deęiřtięi belirlenmiřtir.

Bu alıřmada deęerlendirilen arařtırma tasarımlarına bakıldığında, alıřmaların yedisinin randomize kontrollü tasarımla yürütüldüęü, bunlardan bazılarında kontrol grubu kullandığı, dięer arařtırmalarda ise kontrol grubuna herhangi bir müdahalede bulunulmadığı belirlenmiřtir. İncelenen dięer arařtırmaların ise gözlemsel, nitel ve tanımlayıcı türde yapıldığı belirlenmiřtir. Ayrıca arařtırmalarda CONSORT 2010 Kontrol Listesi kullanılmadıęı, randomize kontrollü ve deneysel arařtırmaların bazılarında örneklem büyüklüęü ve arařtırma gücü hesaplamasıyla ilgili bilgilere ayrıntılı olarak yer verilmedięi görülmüřtür. Arařtırma örnekleminden yařanan kayıplar ve nedenleri, uygulamayı yürütenlerin eęitim, sertifika ve tecrübeleri, olası bias kaynakları, arařtırmanın sınırlılıkları vb. konularda ayrıntılı açıklamaların bulunmaması da arařtırmaların kanıt düzeyinin yorumlanması konusunda güçlük oluřturmaktadır. Saęlık hizmetleri sunucularına cerrahi hemřirelięinde teknoloji kullanımına ve etkilerine yönelik geniř bir bakıř aısı kazandırabilmek için bu derlemeye dahil edilen alıřmaların metodolojik kalite düzeyi Joanna Briggs Institute (JBI) tarafından düzenlenen kontrol formlarıyla deęerlendirilmiř olup; alıřmaların yedisi randomizasyon yaptıkları için düşük riskli olarak kabul edilmiř, on dördünde randomizasyondan bahsetmedięi için yüksek riskli olarak derecelendirilmiřtir.

Küreselleřme ve teknolojik ilerlemelerin etkisiyle saęlık hizmetleri sunumunda farklılıklar ortaya ıkabilmektedir. Bu kapsamda cerrahi hemřirelięinde teknoloji kullanımı ile ilgili alıřmaların sistematiik incelenmesini amaçlayan bu alıřmada, elektronik veri sistemleri, giyilebilir teknolojik sistemler, bilgisayar destekli eęitim sistemleri, mobil teknolojiler ve robotik cerrahi yöntemlerinin kullanımı ve bu teknolojilerin saęlık hizmetleri sunumuna olan etkisi 21 alıřma sonucuna dayanarak tartıřılmıřtır. Cerrahi hemřirelięinde bu teknolojileri kullanmanın; hasta bakımı, hasta takibi, komplikasyonların yönetimi üzerine olumlu etkilerinin olduęu görülmüřtür.

akırlar ve Mendi³¹ hemřirelerin biliřim sistemleri hakkındaki bilgi ve yeterliliklerini ölçerek elektronik saęlık kayıtlarıyla ilgili görüşlerini belirlemek için yaptıęı alıřmasında, hemřirelerin büyük çoęunluęu teknolojik

yöntemlerin hemřirelik uygulamalarında kullanılmasının faydalı olacaęını ifade etmiř ve elektronik saęlık kayıtlarının kullanılmasıyla hastaya verilen saęlık bakımının kalitesinin artacaęını belirtmiřlerdir. Benzer řekilde arařtırmamızda elektronik veri sistemleri kullanımının cerrahi hemřirelięine etkisini belirlemek üzere incelenen alıřmalarda; klinisyen memnuniyetinin arttıęı, iletiřim algısının yükseldięi belirlenmiřtir. Bu sistemleri kullanmanın faydalı olduęu, iř yükünü artırmadıęı ve hemřirelik uygulamalarının teknolojik yöntemlerle bir bakım ortaklığı kurularak verilmesinin daha etkin olacaęı sonucuna varılmıřtır.

Bu derlemede giyilebilir teknoloji kullanımının cerrahi hemřirelięine etkisini deęerlendiren 7 alıřma incelendi. Giyilebilir teknolojinin saęlık alanında kolay kullanımı, verimlilięi artırma ve zamandan tasarruf saęlama gibi avantajları sebebiyle birok biyolojik verinin ölçülmesinde kullanılabilmektedir. Keskin ve ark.’nın³² alıřmasında sanal gereklięin pediatrik hastalarda nonfarmakolojik yöntem olarak kullanımının aęrıyı gidermede etkin bir araç olduęu bulunmuřtur. Literatürle uyumlu olarak, hastalara yanık pansumanı uygulanırken sanal gereklik gözlüęü kullanmanın etkilerini belirlemek için yapılan bir alıřmada, yanık pansumanı sırasında sanal gereklik gözlüęü kullanmanın aęrı, korku ve kaygıyı azaltmada etkili olduęu belirlenmiřtir.¹¹ Giyilebilir teknolojinin cerrahi hemřirelięinde kullanılmasıyla uzaktan hasta izleme sistemlerinin acil ve kritik durumlarda erken uyarı oluřturma potansiyeline sahip olduęu ve bu řekilde hasta güvenlięini iyileřtirmeye katkıda bulunduęu belirlenmiřtir. Ayrıca uzaktan hasta izleme sistemlerinin kullanılmasıyla ilaç hatalarının saptanması ve düzeltilmesinde önemli bir artış ve aęrıda bir azalma olduęu belirlenmiřtir.

Ryhänen ve arkadaşları³³ Finlandiya’da meme kanserli hastalarda standart hasta eęitimi ve internet aracılığıyla verilen eęitimin etkinlięini deęerlendirdięi alıřmasında, hastaların yařam kalitesi, anksiyete düzeyleri ve yan etkilerin yönetimi konusunda istatistiksel açıdan anlamlı bir fark bulunmamıřtır. Buna raęmen internet temelli eęitim verilen deney grubundaki hastaların anksiyete düzeylerinin tedavi sürecinde azaldığı belirlenmiřtir. Bu bilgiler dahil edilen alıřmalarla paralellik göstermektedir. Bilgisayar destekli eęitim ve öęrenme programlarının cerrahi hemřirelięine etkisini deęerlendiren alıřmaların sonucuna baktığımızda; bilgisayar destekli öęrenme programları kullanmanın karmařık bir bakım ortamında bakımı kiřiselleřtirmeyi ve saęlık eęitimine eriřilebilirlięi artırabildięi, akut bakım sürecinde aęrı inanlarını ve tutumlarını modüle etmek için bilgisayar uygulamalarının kabul edilebilirlięini tanımlamaktadır. Ayrıca e-öęrenim programlarını kullanan hemřirelerin hastalarına daha fazla

vakit ayırabildikleri gözlemlenmiştir.

Literatürde mobil teknoloji kullanımı ile ilgili çalışmalar incelendiğinde, mobil teknolojiler ile hatırlatma tekniği gibi özellikler kullanılarak veya hastalara eğitimler verilerek, diyet uyum, bilinçli ilaç kullanımı, sigarayı bırakma, evde egzersiz uygulama ve yaşam kalitesinin artırılması gibi konularda hastalar açısından anlamlı sonuçlar elde edilmiştir.^{34,35} Mobil teknoloji kullanımının cerrahi hemşireliğine etkisinin incelendiği 5 çalışmada; Mobil cihazların kolay bilgi erişimi, e-öğrenme ve işle ilgili iletişime olanak tanıdığı, algılanan ağrı düzeylerinin azaltılmasında önem taşıdığı, öz yeterliliği artırmada önemli bir etkiye sahip olduğunu ve mobil sistemlerin *kişiselleştirilmiş eğitime olanak tanıyıp hastaların yeni sağlık hizmeti modellerinde bilinçli katılımcılar haline gelebileceğini ortaya koymaktadır.*

Cerrahi hemşireliğinde kullanılan teknolojinin sağlık hizmetleri sunumuna etkisi gerek hasta gerek hemşire yönünden günümüze uygun bir şekilde ilerleme göstermektedir. Teknolojik yöntemlerin sağlık hizmetlerinde çalışanların iş yükünü azalttığı, iletişimi güçlendirdiği, veri kaybını önlediği ve hasta takibini kolaylaştırdığı görülmüştür. Aynı zamanda hastalar üzerinde tedaviyi destekleyen teknoloji yöntemleri ile ağrı, anksiyete ve kaygı gibi fizyolojik sorunlar ile başa çıkmak çok daha kolaylaşmıştır. İlaç takipleri, hasta kontrol zamanlarının teknoloji aracılığıyla takibiyle hasta bakım süreci kesintiye uğramadan sürdürülebilmektedir. Robotik cerrahi konusunda endişeler ne yazık ki halen devam etmektedir. Farkındalık yüksek olmasına rağmen bilgi ve tecrübe düzeyindeki eksikliğe robotik cerrahi ekipmanlarının hem pahalı olması hem de her yerde yaygın bir şekilde kullanılmamasından kaynaklı olduğu düşünülmektedir. Teknolojiyi etkin kullanarak hasta bakımında etkili ve çeşitli tedavi yöntemleri üretmenin ve kullanmanın mümkün olduğu sonucuna varılmıştır.

Araştırmanın Sınırlılıkları

Bu sistematik derlemenin sınırlılığı özet metinlerin çalışmaya dahil edilmemesi nedeniyle deneysel veya yarı deneysel makalelere erişmeyi engellemiş olabilir ihtimali ve yöntem bölümünde belirtilen veri tabanlarının taranması ile sınırlıdır.

Bu çalışma sonucunda cerrahi hemşireliği uygulamalarına yeni teknolojik gelişmelerin entegre edilmesiyle hasta bakımı, hasta takibi, komplikasyon yönetimi gibi birçok alanda olumlu sonuçlar elde edildiği belirlenmiştir. Cerrahi hemşireliği alanında kullanılan teknolojilerin elektronik veri sistemleri, giyilebilir teknolojiler, bilgisayar destekli programlar, mobil teknolojiler ve robotik cerrahi olduğu görülmektedir. Cerrahi hemşireliği ve teknolojisi, sağlık

sektörünün ayrılmaz bileşenleri haline gelmiştir. Robotik cerrahi ve minimal invaziv teknikler gibi cerrahi teknoloji ve prosedürlerdeki gelişmelerle birlikte, hemşire ve teknisyenlerin rolü geleneksel görevlerin ötesine geçmiştir. Hemşirelerin teknoloji kullanımı konusunda istekli olduğu fakat teknolojik yöntemlerin daha etkin kullanımı için daha fazla eğitime ihtiyaç duydukları görülmektedir. Sağlık hizmetleri hasta verilerinin toplanması, değerlendirilmesi, takip edilmesi ve bunun sonucunda hastaya holistik bir bakım verilmesini hedefler. Teknolojik yöntemlerin kullanımıyla sağlık hizmetleri sunumunda hasta bakımının kalitesi artırılarak, hastalıkların engellenebileceği, hastanede yatış süresinin düşürülebileceği ve hasta bakım maliyetleri azaltılabileceği böylece kalite göstergesi olan hasta memnuniyetinin artırılabilmesi öngörülmektedir.

Cerrahi prosedürler daha karmaşık ve yenilikçi hale geldikçe, yüksek eğitimli bir hemşire kadrosuna duyulan ihtiyaç da önemli hale gelmektedir. Cerrahi hemşireliğinde teknolojik yöntemlerin etkinliğini ortaya koyan daha fazla çalışma yapılması önerilebilir.

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The Effect of Virtual Reality Application on Pain in Port Catheter Access in Pediatric Oncology Patients: Systematic Review and Narrative Synthesis

Pediyatrik Onkoloji Hastalarında Port Kateter Erişiminde Sanal Gerçeklik Uygulamasının Ağrı Üzerine Etkisi: Sistematiik Derleme ve Anlatı Sentezi

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ABSTRACT

Objective: This study aims to determine the impact of virtual reality (VR) on pain levels during port catheter access in children aged 4-19 years. The secondary objective is to evaluate the effects of VR on pain catastrophizing, fear, anxiety/distress levels, and heart rates.

Methods: This descriptive systematic review includes studies from databases like PubMed, Medline, Cochrane Library, Scopus, ScienceDirect, and others, using keywords such as "oncology," "leukemia," "virtual reality," "pain," "children," and "pediatric." Nine studies were selected based on the PICOS criteria, with a sample of 544 children. The review followed the PRISMA guidelines, and the data were synthesized using a narrative synthesis method.

Results: The studies showed that VR applications significantly reduce pain during port catheter access compared to standard care and other distraction techniques. Additionally, VR effectively reduces pain catastrophizing, fear, anxiety, distress, and heart rates. The application was found to be both effective and safe in managing pain for pediatric oncology patients.

Conclusion: The evidence quality from the included studies ranges from moderate to strong. While the results are promising, further research is necessary to explore the long-term effects of VR on pain management and psychological factors in pediatric oncology patients undergoing chemotherapy. This review is registered with PROSPERO (CRD42023441761).

Keywords: Child, Virtual reality, Oncology nursing, Pain

ÖZ

Amaç: Bu çalışmanın birincil amacı, 4- 19 yaş arası çocuklarda port kateter erişimi sırasında sanal gerçeklik (SG) uygulamasının ağrı düzeyleri üzerindeki etkisini belirlemektir. İkincil amaç ise SG uygulamasının çocukların ağrı felaketleştirme davranışı, korku, anksiyete/stres düzeyleri ve kalp atış hızları üzerindeki etkilerini değerlendirmektir.

Yöntemler: Bu tanımlayıcı sistematiik derlemenin kapsamını PubMed, Medline, Cochrane Library, Scopus, ScienceDirect, Clinical Key, Ulakbim, Web of Science, CINAHL ve OVID veri tabanlarından "onkoloji", "lösemi", "sanal gerçeklik", "ağrı", "çocuk", "çocuklar", "ergen", "pediyatrik" ve "hemşire" anahtar kelimeleri kullanılarak erişilen çalışmalar oluşturmaktadır. Sistematiik derlemenin örnekleme, tarama süreciyle PICOS kriterlerine göre seçilen 9 çalışmadan oluşmaktadır. Bu sistematiik derleme PROSPERO veri tabanına (CRD42023441761) bir protokol ile kaydedilmiştir ve PRISMA akış şeması adımları kullanılarak yürütülmüştür. Çalışmalardan elde edilen verileri sentezlemek için anlatı sentezi yöntemi kullanılmıştır.

Bulgular: Dokuz çalışmaya 4-19 yaş arası toplam 544 çocuk dahil edilmiştir. Port kateter erişimi sırasında SG uygulamalarının ağrı üzerindeki etkilerini standart bakım ve farklı dikkat dağıtma teknikleriyle karşılaştıran çalışmalar, SG uygulamasının pediyatrik onkoloji hastalarında bu işlem sırasında ağrıyı azaltmak için etkili ve güvenli bir yöntem olduğu sonucuna varmıştır. Ayrıca, SG uygulamasının ağrı felaketleştirme davranışını, korkuyu, anksiyete/stres düzeylerini ve kalp atış hızlarını azaltmada etkili olduğu görülmüştür.

Sonuç: Çalışmalardaki kanıt kalitesi orta ile güçlü arasında değişmektedir. Port kateter girişi sırasında SG uygulamalarının ağrı üzerindeki etkilerini araştırmak için daha fazla araştırma yapılması gerekmektedir ve bu alanda daha fazla araştırmaya ihtiyaç olduğunu göstermektedir. Ek araştırmalar, Sanal Gerçekliğin kemoterapi gören kanser hastaları üzerindeki etkilerine ilişkin belirsizliği azaltmak için önemli bir potansiyele sahiptir. Bu çalışma PROSPERO'ya CRD42023441761 olarak kayıtlıdır.

Anahtar Kelimeler: Çocuk, Sanal gerçeklik, Onkoloji hemşireliği, Ağrı.

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INTRODUCTION

Childhood cancers are a major public health problem today. Childhood cancers represent 0.5% to 4.6% of all cancer cases and account for 1% of cancer deaths, with the highest rates found in low-development countries. The World Health Organization estimates that approximately 400,000 children aged 0-19 are diagnosed with cancer each year. Advances in diagnostic and treatment methods have improved early detection and intervention. In high-income countries, over 80% of diagnosed children are cured, while the cure rate is below 30% in low- and middle-income countries.^{1,2}

In recent years, advancements in the treatment processes of childhood cancers have led to positive developments in their prognosis. However, despite being regarded as a promising advancement, the prolonged duration of cancer treatments results in children and parents frequently encountering medical procedures.^{3,4}

One particularly painful and anxiety-inducing procedure in pediatric oncology is the frequent need for intravenous access, which is essential for administering treatments.⁵ A specific type of central venous catheter, particularly port catheters, reduces the need for needle procedures in pediatric oncology patients requiring long-term treatment, thereby making intravenous access procedures—a typically painful and stressful experience—more tolerable. However, the insertion of these catheters under the skin and the routine replacement of the needle, typically every 5-7 days, can be significant sources of discomfort and fear for the child.^{6,7}

Medical procedures frequently induce pain, distress, and anxiety, which can significantly affect comfort levels in children. Consequently, interventions are needed to address pain and anxiety in pediatric patients.⁵ Recent years have seen the increasing use of non-pharmacological distraction techniques to alleviate pain, fear, and anxiety during injection procedures in pediatric patients.⁸⁻¹⁰ This technique distracts the child from the pain, diverts her attention elsewhere and reduces fear of pain. These methods are especially useful in pediatric oncology as they offer a complementary approach to managing distress without the side effects of medications.¹¹ Tools such as kaleidoscopes, distraction cards, bells, music listening, and video games effectively manage pain perception. Additionally, recent studies have demonstrated that virtual reality (VR) can serve as an effective distraction method for reducing procedural pain in children.^{12,13}

VR technology is a distraction method that provides real perceptual stimuli with various visual, auditory, tactile and

olfactory stimuli in the field of health.^{13,14} In this way, virtual reality provides non-pharmacological management of variables such as pain, anxiety and fear by diverting the attention of the individual.^{15,16} VR has been used in children to manage the experience of injections, intravenous access, burn dressings and postoperative pain.^{8,9,12,15}

As seen, the use of non-pharmacological methods in painful procedures in pediatric oncology patients is effective both in the successful completion of the procedure and in the control of pain and many factors. These methods become vital tools in managing pain and anxiety associated with the procedure and contribute to a more positive experience for both patients and healthcare providers.¹¹

AIM

The primary objective of this systematic review and narrative synthesis was to evaluate the impact of virtual reality applications on pain levels during port catheter access in pediatric oncology patients aged 4 to 19 years. In addition to examining pain levels, we also aimed to assess the children's pain catastrophizing behaviors, fear, anxiety/distress levels, and heart rate changes. Through this investigation, we sought to contribute valuable insights into the efficacy of VR as a non-pharmacological intervention for improving the experiences of pediatric patients undergoing painful medical procedures.

Research questions

- Are virtual reality applications effective in reducing pain levels during port catheter access in pediatric oncology patients aged 4 to 19 years?
- What are the effects of virtual reality applications on pain catastrophizing behaviors, fear, and anxiety/distress levels in pediatric oncology patients?
- How do virtual reality applications used during port catheter access impact heart rate changes in pediatric oncology patients?

METHODS

Desing

In this systematic review, in order to minimize the risk of bias, literature search (3 researchers), article selection (4 researchers), data retrieval stage (4 researchers), and quality evaluation of the articles (4 researchers) were performed independently by the researchers. In order for the research process to take place in the appropriate format and quality, a review was performed with a keyword ("virtual reality") within the scope of the study in the Pubmed database and an article was selected in a session where all researchers were together. After the pilot study, each stage was checked again in a single session with

the researchers (4 researchers) and a consensus was reached regarding the differences in opinions and knowledge.

Selection Criteria and Selection of Studies

Studies eligible for this systematic review were selected according to PICOS criteria^{17,18} According to these criteria;

1. **Study group (P):** Pediatric oncology patients aged 0-19 years with port catheters.
2. **Intervention (I):** Using VR goggles during port catheter access.
3. **Comparison (C):** Usual care (not using VR during port catheter access) and using a method other than VR goggles (Ipad, Guided Imagery).
4. **Outcomes (O):** The primary outcome of the study was pain (pain intensity or presence of pain, reaction to pain, as reported in studies). Secondary outcomes will be the results of measurements of anxiety, fear and pulse rate.
5. **Types of Studies (S):** Randomized controlled trials.

In line with this research, systematic, traditional review and meta-analysis studies, case reports, studies with unclear methodology, studies whose full text could not be accessed, studies that were not experimental and studies that did not report results on pain management through VR application were excluded. In this study, the PRISMA flow diagram (2020) was utilized, and the JBI Critical Appraisal Checklist for Randomized Controlled Trials was applied.^{19,20}

Screening Strategy

The searches related to the systematic review were conducted between August 1, 2024 and September 1, 2024. Searches were made from Pubmed, Medline, Cochrane Library, Scopus, Science Direct, Clinical Key, Ulakbim, Web of Science, CINAHL and OVID databases using the keywords "oncology", "leukemia", "Virtual reality", "pain", "child", "children", "adolescent", "pediatric" in accordance with medical subject headings (MeSH). For additional searches, the reference lists of the available sources were also examined.

Data Extraction

In this study, the 'Publication Classification Form on Using Virtual Reality for Pain Management During Port Access in Children' developed by the researchers, taking into account the systematic review studies conducted by Cheng et al.²¹ and Tran Thi et al.²² in the field of nursing with experimental studies using VR application for pain management in pediatric oncology patients, was used as a data collection tool (Table 1). Expert opinion was obtained for the form and the usability of the form was ensured. With the developed form, data on the authors, publication year, countries, methods, sample sizes, number of cases,

average age, intervention types, and the effect of virtual reality goggles on pain and additional outcomes were collected.

Methodological quality assessment

The methodological quality assessment of the studies included in this systematic review was performed using the critical appraisal checklist published by the Joanna Briggs Institute.²⁰ This list for randomized controlled trials consists of 13 items. Each item on the list was evaluated using the options "yes, no, uncertain and not applicable" (Figure 1). The methodological quality level of the included studies was considered "mediocre" when less than 50% of the items were rated "yes", "moderate quality" when 51-80% of the items were rated "yes", and "good quality" when more than 80% of the items were rated "yes".²³

Synthesis of Data

In the study, narrative synthesis method was used to synthesize the data obtained from the studies. Narrative synthesis is defined as a systematic review and synthesis of findings from multiple studies, based on the use of words and text to summarize and explain findings. The aim of the narrative synthesis approach is not to "examine what works" but to "examine how the intervention works". In addition to all these, this synthesis is to ensure the systematic evaluation of process-based study results.²⁴ Narrative synthesis is a method that can be used to synthesize both quantitative and qualitative studies and can be used when the findings of experimental studies included in a systematic review are not similar enough for meta-analysis.²⁵ In this systematic review, meta-analysis of the studies could not be performed because the data collection methods and the parameters evaluated in the studies examined differed. The findings were presented with narrative method.

Research Ethics

This study is a systematic review and is based on studies published in the literature with references cited. Therefore, approval from any institution or individual and ethics committee is not required. Our study was conducted in accordance with the Declaration of Helsinki Principles.

RESULTS

The study findings encompass research on the effect of VR on pain during port access in pediatric oncology patients in the literature. The study population consisted of 1047 studies. Out of these studies, 843 were excluded due to title and abstract mismatch. The full texts of the remaining 204 studies were examined, and based on content inconsistency, 195 studies were excluded, forming a

sample of nine research studies.

Quality Assessment Results of the Studies

When the quality assessment results of the studies were examined, it was determined that one of the randomized controlled experimental studies had a good quality assessment score, while the other six studies had a moderate level of quality (Table 2).

Evaluation of Findings According to the Identified Themes Characteristics of the studies and participants

The studies included in this systematic review were conducted between 2004 and 2024. Gershon et al.²⁶ in the USA, Woltzky et al.²⁷ in Atlanta, Nilsson et al.²⁸ in Sweden, Semerci et al.², Gerçeker et al.⁹ and Savaş et al.²⁹ in Türkiye,

Hundert et al.⁸ in Canada, Caballero et al.³⁰ in Italy and Reitze et al.³¹ in Germany. The studies included 544 children aged 4-19 years.

Characteristics of interventions

In 77.7% (n=7) of the studies included in this systematic review, VR application was compared with standard care. In the study by Woltzky et al.²⁷, which involved 20 children aged 7-14 undergoing cancer treatment, the effects of VR application on pain, anxiety, fear, and pulse were observed. Nilsson et al.²⁸ included 42 children aged 5-18 undergoing cancer treatment to study the effects of VR application on pain and anxiety. Semerci et al.² included 61 children aged 7-18 undergoing cancer treatment to investigate the

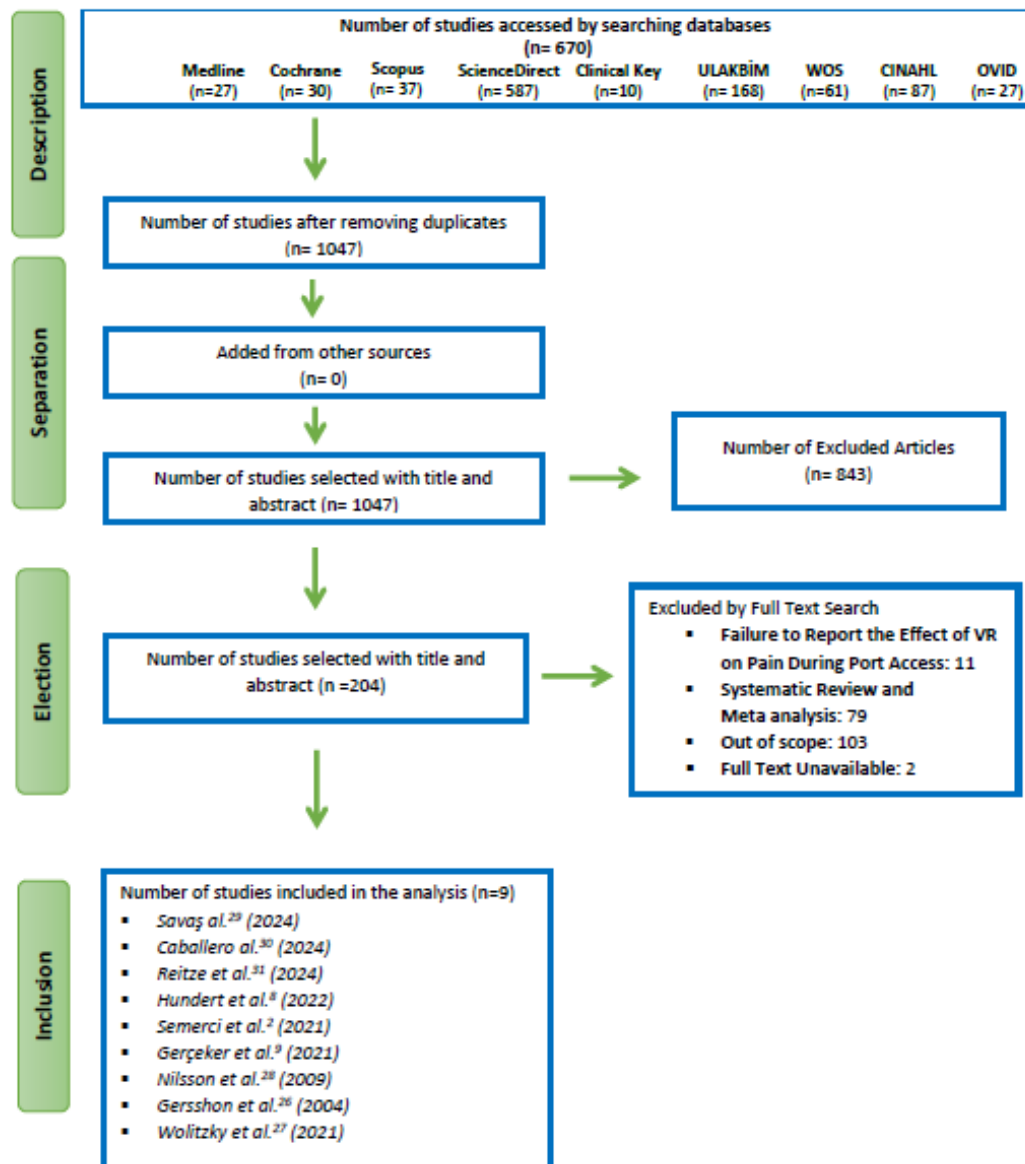


Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Flow Diagram

Table 1. Publication Classification Form on Using Virtual Reality (VR) for Pain Management During Port Access in Children

Author (Publication Year)	Country	Intervention(s)	Sample Size	Mean age, years	Group Feature	Data Collection Tools	Main Results
Gershon et al. ²⁶ (2004)	USA	Virtual reality application during needle insertion into port catheter Non-VR distraction during needle insertion into port catheter	VR (n=22) Non-VR (n=15) Control group (n=15) treated as usual without distraction	7-19 years old Mean= 12.7	Paediatric group with leukaemia, lymphoma, solid tumours No cognitive impairment	VAS (Visual analog scale) CHEOPS (Children's Hospital of Eastern Ontario Pain Scale) Questionnaire form (Cardiac rate)	Virtual reality application during port access is effective in significantly reducing pain and anxiety levels of children. Virtual reality application during port access is effective in reducing the pulse values of children.
Wolitzky et al. ²⁷ (2005)	USA - Atlanta	Virtual reality application during needle insertion into port catheter	VR (n=10) Control group (n=10)	7-14 years old Mean= 10.50 Mean VR= 11.20 Mean - Control= 9.8	Various paediatric oncology patients	CHEOPS (The children's hospital of eastern ontario pain scale) How-I-Feel VAS (Visual analog scale) Questionnaire form (Cardiac rate)	Virtual reality application during port access is effective in significantly reducing pain and anxiety levels of children. Virtual reality application during port access is effective in reducing the pulse values of children.
Nilsson et al. ²⁸ (2009)	Sweden	Virtual reality application during needle insertion into port catheter	VR (n=21) Control group (n=21)	5-18 years old Mean -VR=11 Mean - Control= 11	Leukaemia Paediatric group with brain tumours and solid tumours	CAS (Colour Analogue Scale) FAS (Facial Affective Scale) FLACC (Face, Legs, Activity, Cry, Consolability scale) Questionnaire form (Cardiac rate)	Virtual reality application during port access is not effective in significantly reducing the pain levels of children. Virtual reality application during port access is effective in significantly reducing the distress levels of adolescents. Virtual reality application during port access is not effective in significantly reducing the pulse rate of children.
Gerçeker et al. ⁹ (2021)	Türkiye	Virtual reality application during needle insertion into port catheter	VR (n=21) Control group (n=21)	6-17 years old Mean - VR= 11.2±3.1 Mean - Control= 11.7±3.2	Various paediatric oncology patients No visually impaired No cognitive impairment Huber Port pin not inserted before	Wong-Baker Faces Pain Rating Scale (WBS) The Child Fear Scale (CFS) The Children's Anxiety Meter-State (CAM-S)	Virtual reality application during port access is effective in significantly reducing pain, fear and anxiety levels of children.
Semerci et al. ² (2020)	Türkiye	Virtual reality application during needle insertion into port catheter	VR (n=35) Control group (n= 36)	7- 18 years old Mean - VR= 11.69±3.36 (7-18) Mean - Control= 11.67±3.55 (7-17)	Various paediatric oncology patients No cognitive impairment	Wong-Baker FACES Pain Rating Scale.	Virtual reality application during port access is significantly effective in reducing the pain level of children.

Table 1. Publication Classification Form on Using Virtual Reality (VR) for Pain Management During Port Access in Children (Continued)

Author (Publication Year)	Country	Intervention(s)	Sample Size	Mean age, years	Group Feature	Data Collection Tools	Main Results
Hundert ⁸ (2022)	Canada	Virtual reality application during needle insertion into port catheter Ipad application during needle insertion into port catheter	VR (n=20) Ipad group (n=20)	8-18 years old Mean= 12.4 Mean - VR= 12.1±3.0 Mean - Ipad= 12.6±3.6	Actively receiving oncological treatment (ALL, Brain Tumour, Lymphoma)	NRS (Numeric Rating Scale) CFS (The Child Fear Scale) Pain Catastrophizing Pain Catastrophizing Scale for Children (PCS-C) Pain Catastrophizing Scale for Parents (PCS-P)	Virtual reality application during port access is not effective in significantly reducing the pain levels of children. Virtual reality application during port access is not effective in significantly reducing the likelihood of children experiencing distress. Virtual reality application during port access is effective in significantly reducing children's fear levels. Virtual reality application during port access is effective in reducing the rate of catastrophizing pain.
Caballero et al. ³⁰ (2024)	Italy	Virtual reality application during needle insertion into totally implantable venous access devices (TIVAD).	VR (n=60) Control Group (n=60)	4-18 years old Mean - VR= 10.5 Mean - Control= 9.2	Pediatric oncology patients	Faces Pain Scale-Revised (FPS-R) State-Trait Anxiety Inventory for Children (STAIC) Questionnaire for VR experience Nurse assessment	Children in the intervention group reported higher satisfaction compared to those in the control group. Pain levels were also found to be lower in the group using virtual reality (VR). Older children benefitted more from this method, as they could engage better with the VR experience. Healthcare professionals expressed satisfaction with the assistance provided by VR in managing TIVAD procedures.
Reitze et al. ³¹ (2024)	Germany (Hannover Medical School)	Virtual Reality (VR) during port/vein punctures	VR (n=17) Control Group (n=21)	6-18 years old Mean- VR+ Control= 11.5	Pediatric Oncology Patient	Pediatric Quality of Life Inventory (PedsQL) Numerical Rating Scale (NRS) (Faces Pain Scale - Revised) FPS-r Modified Yale Preoperative Anxiety Scale - Short Form (mYPAS-SF) Behavioural Approach-Avoidance and Distress Scale (BAADS) Stress Coping Questionnaire for Children and Adolescents (SSKJ3-8R)	Pain levels were measured before, during, and after potentially painful interventions using the FPS-r (for ages 6–9) and NRS (for ages 10–18) scales. In the group receiving CoS, pain levels were found to be high during the intervention, whereas the group using virtual reality (VR) reported lower pain levels. The distress levels in the VR group significantly decreased compared to SoC group. Anxiety levels were also found to be lower in the VR group both before and during the intervention.
Savaş et al. ²⁹ (2024)	Türkiye	VR application and respiratory sensor insertion during needle insertion into port catheter Non-VR application and respiratory sensor insertion during needle insertion into port catheter	VR (n=31) Control group (n=31)	6-12 years old Mean - VR= 9.33 Mean - Control= 9.74	In the pediatric oncology and hematology clinic of a city hospital in Istanbul	Descriptive Information Form Wong-Baker Faces Pain Rating Scale (WBS) Child Fear Scale (CFS) Children's State Anxiety Satisfaction Scoring Visual Analog Scale (VAS), ADXL354 Sensor	Virtual reality application during port access is effective in significantly reducing children's pain and anxiety levels. Virtual reality application during port access is significantly effective in reducing children's fear and anxiety levels. Virtual reality application during port access is effective in reducing respiratory rate. Virtual reality application during port access is effective in decreasing the satisfaction score.

Table 2. JBI Critical Appraisal Checklist for Randomized Controlled Trials Questions

Studies	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	S12	S13	Quality Score
Gershon et al. ²⁶	Y	N	Y	N	N	N	Y	Y	Y	Y	Y	Y	Y	Middle (69.2)
Wolitzky et al. ²⁷	Y	N	Y	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Middle (76.9)
Nilsson et al. ²⁸	Y	N	Y	N	N	N	Y	Y	Y	Y	Y	Y	Y	Middle (69.2)
Gerçeker et al. ⁹	Y	N	Y	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Middle (76.9)
Semerçi et al. ²	Y	N	Y	N	N	N	Y	Y	Y	Y	Y	Y	Y	Middle (69.2)
Hundert et al. ⁸	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Good (84.6)
Cabellero et al. ³⁰	Y	U	Y	N	N	N	Y	Y	Y	Y	Y	Y	Y	Middle (69.2)
Reitze et al. ³¹	Y	U	Y	N	N	N	Y	Y	Y	Y	Y	Y	Y	Middle (69.2)
Savaş et al. ²⁹	Y	N	Y	Y	N	NA	Y	Y	Y	Y	Y	Y	Y	Middle (76.9)
Question Quality Appraisal	100%	11.1%	100%	11.1%	0%	33.3%	100%	100%	100%	100%	100%	100%	100%	

S; Question, Y; Yes, N; No, U; Unclear, NA; Not Applicable

impact of VR application solely on pain. Gerçeker et al.⁹ included 42 children aged 6-17 undergoing cancer treatment and examined the effects of VR application on pain, fear, and anxiety. Caballero et al.³⁰ aimed to evaluate the usefulness of VR in reducing anxiety and pain in children and facilitating the work of the nursing team in a study conducted with 120 pediatric oncology patients (VR=60, Control=60). Reitze et al.³¹ examined the interventional reduction of pain, anxiety and distress using VR compared to standard care in a study conducted with 20 pediatric cancer patients (VR=17, Control=21) aged 4-17 in Germany. Savaş et al.²⁹ investigated the effect of a biofeedback-based virtual reality game on pain, fear and anxiety levels during port needle placement in a study conducted with 62 pediatric cancer patients (VR=31, Control=31).

In this systematic review, 22.2% (n=2) of the studies addressed have compared VR application with different distraction techniques other than standard care. Gershon et al.²⁶ conducted a study involving 52 children aged 7-19 undergoing cancer treatment, comparing three groups: standard care group (n=15), Non-VR distraction group (n=15), and VR distraction group (n=22). Pain and anxiety parameters were evaluated in these three groups. Similarly, Hundert et al.⁸ included 40 children aged 8-18 undergoing cancer treatment and compared VR application with iPad distraction method.

Characteristics of Pain Scales

The effects of VR applications on pain during port catheter access have been examined in the studies included in this systematic review. Gerson et al.²⁶ and Woltzky et al.²⁷ used CHEOPS, Caballero et al.³⁰ used FPS-R (Face Pain Scale-Revised) to scale pain, while Gerçeker et al.⁹, Semerçi et al.² and Savaş et al.²⁹ used WBS. Nilsson et al.²⁸ used both the CAS (Color Analog Scale) for self-rating children and the FLACC (Face, Legs, Activity, Crying, Consolation Scale) for

scaling pain. Reitze et al.³¹ used FPS-r for medications for ages nine and under, and NRS for expenses for ages and above.

Characteristics of other scales

Only 11.1% (n=1) of the studies included in this systematic review have examined the effects of VR, a form of distraction technique, on fear catastrophizing in children undergoing cancer treatment. In the studies conducted Hundert et al.⁸, fear catastrophizing scores were measured using the Pain Catastrophizing Scale for Children (PCS-C). Only 44.4% (n=4) of the studies included in this systematic review have examined the effects of VR, a form of distraction technique, on the level of fear in children undergoing cancer treatment. Gerçeker et al.⁹ and Hundert et al.⁸ utilized the PCS-C to assess fear levels in their studies. While Caballero et al.³⁰ used the State-Trait Anxiety Inventory for Children (STAIC) to measure the level of fear, Savaş et al.²⁹ used Children's State Anxiety.

Only 44.4% (n=4) of the studies included in this systematic review have investigated the effects of VR application, another form of distraction technique, on anxiety levels in children undergoing cancer treatment. Wolitzky et al.²⁷ employed the How-I-Feel scale, Gerçeker et al.⁹ used the Children's Anxiety Meter-State (CAM-S), Nilsson et al.²⁸ employed the Facial Affective Scale (FAS).

33.3% (n=3) of the studies in the systematic review have examined the effect of VR, a form of distraction technique, on the heart rate of children undergoing cancer treatment. In their respective studies, Wolitzky et al.²⁷, Gershon et al.²⁶ and Nilsson et al.²⁸ evaluated heart rates using pulse monitors by nurses and researchers before, during, and after port catheter access in both VR and non-VR application groups.

In this systematic review, 11.1% (n=1) of the included cases were studied on how children undergoing cancer

treatment, which provided attention distribution methods, were made on breathing, which provided maintenance of virtual reality. Respiratory rates were obtained using the ADXL354 sensor. The main features of the sensor are low sound intensity, high sensitivity and programmable digital high and low pass filters. Data were recorded on a 62 Hz body recording, which is sufficient to obtain a cardiorespiratory signal.

Only 22.2% (n=2) of the studies included in this systematic review examined the satisfaction level of the virtual reality glasses application, which is a distraction method. Caballero et al.³⁰ examined the satisfaction levels of both patients and nurses using a Likert scale with options such as Preference, Facilitation, Comfort, Usefulness, and Cooperation. Savaş et al.²⁹ scored the VAS 0 as "Not satisfied at all" and 10 as "Very satisfied" to assess the satisfaction of patients with the port catheter needle placement procedure.

The Effects of virtual reality goggles on pain behaviors

Children diagnosed with cancer benefit from the use of port catheters during their treatment process. Accessing the existing port catheter is a painful procedure for children. Utilizing distraction techniques during port catheter access proves effective in managing pain in this demographic. In all studies included in this systematic review (n=10), the effects of VR applications on pain during port catheter access were examined. In 77.7% (n=7) of these studies, VR application was compared with standard care. The comparison of VR application with standard care was conducted by Wolitzky et al.²⁷, Nilsson et al.²⁸, Gerçeker et al.⁹, Semerci et al.², Caballero et al.³⁰ included children aged 7-14 undergoing cancer treatment (n=20) in their study. The evaluation was carried out using the Visual Analog Scale (VAS). Parents, children, and nurses assessed pain levels before and after the procedure. The study results indicated that VR during port catheter access significantly reduced children's pain levels. Nilsson et al.²⁸ included pediatric oncology patients aged 5-18 (n=59) in their study. Both self-assessment using CAS and nurse assessment using FLACC were employed for evaluation. The study found that VR during port catheter access did not significantly reduce children's pain levels. Gerçeker et al.⁹ included children aged 6-17 undergoing cancer treatment (n=42) in their study. The evaluation was conducted using the Wong-Baker Faces Pain Rating Scale (WBS). The study concluded that VR during port catheter access significantly reduced children's pain levels. In the study by Semerci et al.², children aged 7-18 undergoing cancer treatment (n=61) were included. The evaluation was done using the WBS. The study found that VR application during port catheter access significantly reduced children's pain levels.

Caballero et al.³⁰ used Faces Pain Scale-Revised (FPS-R) to assess the pain of pediatric oncology patients (n=120). The study found significant distributions in the range of VR opening during the opening of the connection point temperature. Reitze et al.³¹ used FPS-r (6-9 years old) and NRS (10-18 years old) before, during and after the intervention to increase the pain level of 38 pediatric oncology patients. Although the pain levels were very low before and after the intervention, there was an increase in pain perception during the intervention. In particular, the control group average pain ranged from 0.22 to 2.5 and 0.33. The VR groups were found to have significantly lower pain during the intervention, from 0.08 to 1.58 and 0.53. ($P < 0.05$): This shows that patients experience significantly lower pain levels when using VR glasses during a painful puncture. Savaş et al.²⁹ used WBS to listen to the impressive pain written by 6-12 year olds in Türkiye. As a result; the mean pain scores of patients in VR and controls were found to be 1.67 ± 1.13 and 3.48 ± 0.81 , respectively, and reported a significant difference ($P < 0.001$).

In these six studies, various pediatric oncology patients with ages ranging from 4 to 19, who did not have cognitive impairments, were included.^{2,9,27-30} When evaluating the pain levels of groups that received VR application during port catheter access and comparing them with groups that received standard care, it was observed that the groups with VR application had significantly lower pain levels. In these studies, VR applications were found to be highly effective interventions in reducing pain during painful procedures when compared to standard care.

In 11.1% of the studies (n=1), a three-group design was used where VR application and standard care were combined with a non-VR distraction technique. Gershon et al.²⁶ included pediatric oncology patients aged 7-19 (n=52) in their study. The assessment was done using the Visual Analog Scale (VAS). In this study, both nurses, parents, and children were asked to evaluate pain.²⁷ While no significant differences in pain were observed between groups before the port catheter access procedure, a reduction in pain levels was noted during the procedure in groups where both VR and non-VR distraction techniques were applied.

22.2% (n=2) of all studies included in this systematic review have compared VR application with different distraction techniques other than standard care. In their study, Hundert et al.⁸ included children aged 8-18 undergoing cancer treatment (n=40). The study compared VR application with iPad distraction application. In Hundert et al.'s study, when the effect of the iPad application on pain during port catheter access was examined, participants reported feeling three times more pain compared to the VR

application.⁸

The effects of virtual reality on heart rate and respiratory rate

In 33.3% (n=3) of the studies within this systematic review, the effects of VR applications on heart rate, a physiological indicator, were examined. Nilsson et al.²⁸, Gershon et al.²⁶ and Wolitzky et al.²⁷ assessed heart rates using pulse monitors by nurses and researchers before, during, and after port catheter access in both VR and non-VR application groups.^{26–28} In Wolitzky et al.'s²⁷ study, during the procedure, heart rates were found to be significantly lower in the VR application groups among children who showed no difference in heart rates before the procedure in both groups.²⁷ In Nilsson et al.'s²⁸ study, heart rates were measured by a nurse using a pulse oximeter before, during, and after the procedure. Although a decrease in heart rate was observed in the VR group, no significant difference was found.²⁸ In Gershon et al.'s²⁶ study, heart rate was monitored by researchers during port catheter access. During the procedure, the heart rate of the group in which VR was applied was found to be at the lowest level, showing a lower heart rate compared to the group without VR application.²⁶

The effects of virtual reality application on pain catastrophizing behavior

Pain catastrophizing experiences can assess the effectiveness of distraction interventions. In 11.1% (n=1) of the studies included in this systematic review, the effectiveness of VR applications on pain catastrophizing behavior was evaluated. Children can report their pain catastrophizing experiences during procedures, and parents can also report their children's pain catastrophizing experiences during procedures. In Hundert et al.'s study, children in the VR group reported lower pain catastrophizing during port catheter access compared to the iPad group. However, parents' reports of their children's pain catastrophizing were higher in both groups than the children's own reports.⁸

The effects of virtual reality application on fear

In 33.3% (n=3) of the studies included in this systematic review, which were among the distraction methods, the impact of VR on the level of fear in children undergoing cancer treatment was examined. Gerçeker et al.⁹ conducted a study where fear levels reported by children and parents were evaluated before and after venous port access. According to the study data, there was no significant difference between groups in fear levels before venous port access. However, after the procedure, fear levels reported by children and parents significantly

decreased. The study concluded that the VR application during venous port access significantly reduced the fear levels of children.

In the study by Hundert et al.⁸ fear levels reported by children were found to be low in both groups (VR-Ipad) according to the study data. Additionally, participants who received the Ipad application had fear scores three times higher than those who received the VR. Fear scores before the procedure in both the VR and Ipad groups were higher than fear scores reported during the procedure.

In the study conducted by Savaş et al.²⁹ there was no statistically significant difference between the pre-procedure mean fear scores of children in the VR and control groups. However, post-procedure, the mean fear score of children in the intervention group was measured at 1.46 ± 0.50 , while that of the control group was 2.80 ± 0.70 . This finding indicates that the fear levels of children in the intervention group were significantly lower compared to those in the control group ($P < 0.001$).

The effects of virtual reality application on anxiety/worry/distress

In 88.8% (n=8) of the studies included in this systematic review, which were among the distraction methods, the impact of VR on anxiety/worry/distress levels in children undergoing cancer treatment was examined.

Gerçeker et al.⁹ evaluated anxiety levels reported by children and parents before and after venous port access in both the control and VR groups. While the control group showed no significant change, the VR group experienced a significant reduction in anxiety levels. In the VR group, self-reported anxiety dropped by 2 points, whereas no significant decrease was noted in the control group, demonstrating the effectiveness of VR in reducing anxiety during port needle insertion.

In their study, Hundert et al.⁸ conducted assessments before and after the procedure using an 11-point Numeric Rating Scale (NRS), where children, parents, and nurses participated. Additionally, parents reported their distress levels using the "Parent Distress Questionnaire" following the child's procedure. The study's findings revealed that participants who underwent the Ipad application had a 4.1 times higher likelihood of experiencing distress compared to participants who underwent the VR application.

In their study, Nilsson et al.²⁸ conducted assessments using the Facial Affective Scale (FAS). During the procedure, the distress level significantly increased in both groups compared to before the procedure. After the procedure, the FAS scores significantly decreased in both groups. It

was found that distress significantly decreased in children who underwent the VR application.

In their study, Wolitzky et al.²⁷ included children (n=20) aged between 7 and 14 years who were undergoing cancer treatment. The assessment was conducted using the "How I Feel" questionnaire and Visual Analog Scale (VAS) by parents, children, and nurses before and immediately after the procedure. When examining the study findings, no significant difference in anxiety levels between the groups was observed before the procedure ($P > 0.05$). However, during the assessment conducted during port access, it was concluded that the VR significantly reduced children's anxiety levels.

In their study, Gershon et al.²⁶ assessed anxiety using the Visual Analog Scale (VAS) and the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) before and after the port access procedure, with retrospective scores due to logistical challenges in obtaining real-time ratings. No significant difference in anxiety levels was found between the groups prior to the procedure ($P > 0.05$). However, children in the non-VR control group exhibited significantly more muscle and leg tension compared to those who underwent VR ($P < 0.05$), despite no significant difference in overall CHEOPS scores. The study concluded that while anxiety levels were similar before the procedures, VR significantly reduced anxiety levels in children during port access.

In the study conducted by Reitze et al.³¹ distress and anxiety levels were assessed using VR goggles. The distress measured by the BAADS scale was found to be an average of 2.6 in the intervention group and 3.1 in the standard of care (SOC) group during the procedure, with this difference being statistically significant ($P < 0.01$). Anxiety levels were recorded as an average of 28.6 in the VR group and 33.5 in the SOC group, demonstrating a significant reduction ($P < 0.001$). These findings indicate that VR goggles significantly reduce anxiety during painful procedures.

In the study by Savaş et al.²⁹ there was no statistically significant difference in pre-procedure anxiety scores between the children in the intervention and control groups. However, post-procedure, the mean anxiety score for children in the VR group was measured at 2.57 ± 1.23 , while the score for the control group was 5.38 ± 1.72 ($P < 0.001$). These results indicate that the anxiety levels in the VR group were significantly lower compared to the control group.

In their study, Caballero et al.³⁰ analyzed anxiety levels using STAIC scores, revealing a significant reduction in the VR group with an average score of 1.25 compared to 2.03

in the control group. This finding indicates a notable 38.52% decrease in anxiety among patients in the VR group. Furthermore, anxiety levels were consistently lower in the VR group compared to the control group across all age groups and genders. However, it is noteworthy that no statistically significant difference in anxiety levels was observed between the groups in the 8 to 11-year-old age group.

DISCUSSION

This systematic review was conducted to investigate the literature on the effect of VR port catheter access on pain level in children aged 4-19 years, and to evaluate children's pain catastrophizing behaviour, fear, anxiety/ anxiety/ distress level and cardiac rate. When the literature was examined, it was found that the effect of virtual reality exposure on anxiety and pain levels in pediatric patients.^{5,16,32} The effect of virtual reality on pediatric pain, fear and anxiety during procedures using needles in pediatric patients³³⁻³⁵ and the effects of distraction on pain reduction during invasive procedures in children with cancer²¹, systematic review and meta-analysis studies were found, but no systematic study specifically examining the effects of virtual reality goggles used during port catheter access on pain and fear was found. In this context, this is the first study to examine the effect of virtual reality on the pain and fear of pediatric oncology patients.

Needle procedures, mostly intravenous cannulation, are the most common cause of pain in children in the hospital setting. Although this pain experience in children is repeatedly reported in the literature, its management remains inadequate. Pain management should address the physical and psychosocial process of the child as a whole.¹² The findings of this systematic review show that the use of VR in pediatric oncology patients is effective in reducing the pain symptom during port catheter access. In the included studies, it was found that the pain levels of patients using VR were significantly lower than the control groups.^{2,8,9,26-28,30} In addition to pain assessment, pain catastrophizing of pediatric oncology patients was also evaluated in the studies, and it was found that the pain catastrophizing experienced by children was significantly reduced by distraction techniques. While VR significantly reduced pain catastrophizing in children, no significant results were found on parents.⁸ VR allows pediatric oncology patients to feel less pain by distracting them through visual and auditory stimuli during port catheter access. In this way, VR can reduce the use of analgesic drugs and provide protection from the side effects of drugs. As a result of the review, the use of VR technology is supported as an alternative treatment method to provide pain

management and control stress levels of pediatric oncology patients.

Children undergoing cancer treatment are exposed to many procedures during their treatment. Children experience fear during access to the venous port, one of these procedures. Due to the fear experienced, disruptions may occur in the treatment process of children. When the literature is examined, there are studies on the effectiveness of distraction methods in managing fear.^{5,28} In the studies included in this systematic review, fear levels of pediatric oncology patients were examined in addition to pain. In the studies, it was concluded that the fear levels of the VR-treated groups were lower compared to other groups.^{8,9} VR experience can positively affect the emotional state of patients and reduce their sensitivity to fear. In this way, patients' compliance with treatment may increase, their hospital experiences may improve positively, and their psychosocial well-being is positively affected.

Another parameter analysed in the studies included in this systematic review is anxiety/worry/ distress. Anxiety is a common problem affecting many people today. The advancement in technology in recent years has significantly affected the psychological and mental field. In this context, VR technology stands out as an innovative approach in the treatment of anxiety. The findings of this systematic review show that the use of VR in pediatric oncology patients is effective in reducing the anxiety symptom that occurs during port catheter access. In the included studies, it was found that the anxiety levels of patients using VR were significantly lower than the control groups.^{8,9,26-31} The literature shows that VR have positive effects on anxiety.⁵ However, it is important to better understand the effects of VR through more comprehensive and long-term research. Future studies may provide more information on how this technology can be used in anxiety management and help to develop more effective treatment methods in this field.

Another parameter evaluated in the studies included in the systematic review was cardiac rate. Cardiac rate is closely related to emotional states such as stress and anxiety. Stressful situations may increase cardiac rate, while relaxation and relaxation states may decrease cardiac rate. In the studies included in the systematic review, the effect of standard care and VR goggles application on cardiac rate during port access was evaluated, but the effect of a different distraction technique on cardiac rate was not examined. In line with the study findings, it was observed that VR applications reduced cardiac rates in children during port access.²⁷⁻²⁹

In addition to the benefits of using VR goggles in pain management for pediatric oncology patients in the clinical setting, some difficulties and disadvantages are also noteworthy. Reasons such as the high cost of the application, physical discomfort, weight, feeling of pressure on the head and face or limiting mobility, and personnel training negatively affect the use of VR goggles by patients.⁴ Therefore, the use of VR goggles in pediatric oncology patients should be done in accordance with the individual needs and preferences of the patients.

When the evidence quality of the studies included in this systematic review was analysed, it was found to be of good quality. This result is valuable in terms of showing that the information provided by the studies is reliable.

Limitations

Considering the limitations of the systematic review, firstly, in three studies included in the systematic review, the effectiveness of VR application was compared with another distraction method.^{8,26} It is thought that this may have affected the results of comparing the pain level in the control groups. Another limitation is that the effect of VR application on pain was evaluated with different measurement tools in the studies included in the systematic review. This situation prevents the statistical analysis of the studies, so it is thought to reduce the level of evidence.

The systematic review concluded that the application of VR glasses is an effective and safe method to reduce pain during port catheter access in pediatric oncology patients. In addition to pain, it was concluded that it was effective in reducing pain catastrophizing behaviour, fear, anxiety/anxiety/distress level and cardiac rates. However, further clinical trials are important to more precisely evaluate the effectiveness of the application and to learn more about its potential disadvantages. Furthermore, further studies are needed on how to integrate VR goggles in the clinical setting and how to incorporate them into management strategies, taking into account patients' preferences and comfort.

Etik Komite Onayı: Bu çalışmada, örneklem kapsamına alınan araştırma makaleleri erişime açık olan arama motoru ve elektronik veri tabanlarından alındığı için etik izin gerektirmemektedir. Ayrıca incelenen makaleler kaynakçada gösterilmiştir.

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Effectiveness of the Mindfulness-Based Interventions for Caregivers of Patients with Amyotrophic Lateral Sclerosis: A Scoping Review

Amyotrofik Lateral Skleroz Hastalarının Bakım Verenlerine Yönelik Farkındalık Temelli Müdahalelerin Etkinliği: Kapsam Derlemesi

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ABSTRACT

Objective: This study aimed to evaluate and summarize the literature on the effectiveness of mindfulness-based interventions for informal caregivers of the patients with ALS.

Methods: A scoping review was conducted using electronic databases such as EBSCO, Scopus, PubMed and Web of Science. Total of 475 studies were identified by searching through databases and other sources. After screening the titles and abstracts, 19 studies remained for full text review. Questions such as 'What is the effect of awareness based interventions on caregiver burden for caregivers of ALS patients?' were sought to be answered. The PRISMA flowchart was adhered to throughout the process.

Results: 6 studies were included in this scoping review; one RCT, two pre-post design studies, one qualitative study and two cohort study. The fact that studies on Mindfulness-Based Interventions for caregivers of patients with ALS have only been available since 2016, and the number of them is small, and demonstrates the lack and novelty of trials on this topic. The findings of this scoping review suggest that mindfulness-based interventions can significantly alleviate caregiver burden, enhance quality of life, and improve psychological well-being, including reductions in anxiety and depression, among caregivers of patients with ALS.

Conclusion: Despite the limited number of studies, the evidence supports the potential effectiveness of mindfulness-based approaches as a valuable support strategy for this population. It is believed that further research is required on this topic.

Keywords: Amyotrophic lateral sclerosis, motor neuron disease, caregiver burden, mindfulness

ÖZ

Amaç: Bu çalışmanın amacı, ALS hastalarının bakım verenlerine yönelik farkındalık temelli müdahalelerin etkinliğine ilişkin literatürü değerlendirmek ve özetlemektir.

Yöntemler: EBSCO, Scopus, PubMed ve Web of Science gibi elektronik veri tabanları kullanılarak literatür taraması gerçekleştirildi. Toplam 475 çalışmaya erişildi. Başlıklar ve özetler incelendikten sonra tam metin incelemesi için 19 çalışma dahil edildi. "ALS hastalarının bakım verenleri için farkındalık temelli müdahalelerin bakım veren yükü üzerindeki etkisi nedir?" gibi sorulara yanıt arandı. PRISMA akış şemasına uygun hareket edildi.

Bulgular: Bu kapsam derlemesine bir tane randomize kontrollü, iki tane ön test-son test tasarımlı, bir tane nitel, iki tane kohort çalışma olmak üzere 6 çalışma dahil edildi. ALS hastalarının bakım verenlerine yönelik farkındalık temelli müdahaleler üzerine yapılan çalışmaların 2016'dan beri devam etmesi, bu konunun güncelliğini koruduğunu gösterirken, çalışmaların sayısının yetersizliği de alandaki araştırma eksikliğini vurgulamaktadır. Araştırmalar, farkındalık temelli müdahalelerin ALS hastalarının bakım verenlerinin bakım yükü, anksiyete ve depresyon düzeylerini azaltma, yaşam kalitesi düzeyini artırma, psikolojik refahı iyileştirme potansiyelini vurguladığı görülmektedir.

Sonuç: Sınırlı sayıda çalışmaya rağmen, kanıtlar farkındalık temelli yaklaşımların bu popülasyon için değerli bir müdahale olarak potansiyel etkinliğini desteklemektedir. Konuyla ilgili daha fazla çalışmaya ihtiyaç olduğu düşünülmektedir.

Anahtar Kelimeler: Amyotrofik lateral skleroz, motor nöron hastalığı, bakıcı yükü, farkındalık

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INTRODUCTION

Amyotrophic lateral sclerosis (ALS) is an adult-onset neurodegenerative condition of both upper and lower motor neurons in the brain and spinal cord resulting in dysfunction of the voluntary muscles.¹ Clinical presentation of ALS is varied, but primary symptoms are associated with motor dysfunction, such as muscle weakness, cramping, fasciculations, limb palsy, dysarthria, and dysphagia, and approximately 50% of patients reported cognitive and behavioral abnormalities. There is no known treatment, and death from respiratory compromise typically occurs within 3 to 5 years.^{2,3}

The progressive nature of disease leads to a rising need for care in activities of daily living. It is known that they spend about 11 hours per day in caregiving, even while they have been receiving no professional caregiver assistance.^{4,5} The caregivers of the patients with ALS, commonly informal caregivers such as a member of the family, are adversely affected by clinical impairments of the disease. Although ALS is a rare disease, it results in an increased social, economic, and personal burden for both patients and their primary caregivers.^{6,7}

Caregiver burden is the impact of the caregiving role to the patients with progressive chronic disease on the physical and emotional health of caregivers.^{6,8} Both the caregiver and patient related factors affect the caregiver burden. In a systematic review, it was reported that “behavioral impairments” and “physical functioning” of the patient and “feeling of depression” of the caregiver affect the caregiver burden with moderate to high-quality evidence.⁶ Moreover, studies have shown that reduced caregiver well-being impacts patient well-being negatively.^{9,10}

Currently, supportive interventions for caregivers are available and to be developed. One of the new interventions is a mindfulness-based intervention that may help manage the caregiver burden. Mindfulness is defined as paying attention in a specific way on purpose, in the present moment, and non-judgmentally and based on Buddhist philosophies.¹¹ Mindfulness is a simple way of relating to all experiences that have the potential to reduce suffering and pave the way for positive personal transformation. It is a fundamental psychological process that can change how the person responds to the unavoidable challenge of life, including suicidal ideation, chronic depression, and psychotic delusions.^{12,13} Mindfulness is also defined as both a skill and practice: The practice of mindfulness breeds the ability to be mindful. The stronger individual's ability to adopt a mindful state in the constant ups and downs of life, the less pain one will

suffer.¹⁴

In recent years, researchers have focused on mindfulness as a protective factor against the effects of challenging life events¹⁵ and increasing evidence supports that mindfulness-based interventions reduce caregiver burden.¹²

Those who provide care for individuals with severe chronic conditions, such as amyotrophic lateral sclerosis (ALS), are at an elevated risk of developing depressive and anxiety disorders, as well as a diminished quality of life.¹⁶ There are limited studies compiling information about interventions for caregivers of patients with ALS.¹⁶⁻¹⁹ The results of a study demonstrated a positive correlation between mindfulness and quality of life, as well as a negative correlation between mindfulness and the level of caregiver burden. Those acting in a caring capacity who demonstrate high levels of mindfulness tend to perceive themselves as experiencing lower levels of burden. Those who possess this quality experience reduced levels of anxiety and depression and exhibit a superior quality of life in comparison to individuals who lack this attribute. The study indicates that mindfulness may serve as a preventive factor against the adverse effects associated with caregiving. It can be posited that an enhancement in the level of mindfulness may serve as a protective factor against the onset of caregiver burden. Consequently, the implementation of mindfulness-based interventions may prove an efficacious strategy for the enhancement of the quality of life of the caregiver.¹⁶ A study was conducted to investigate the feasibility and acceptability of a therapeutic group intervention promoting self-care, problem solving and mindfulness to informal caregivers of individuals with ALS. The findings indicated that the intervention was both feasible and acceptable for this population.¹⁹

However, a general view of mindfulness-based interventions for caregivers of the patients with ALS and their impact on care burden is lacking. This issue is regarded as significant due to the pivotal role that caregivers play in the management of ALS disease. It is therefore vital that interventions are provided to support the psychological state and care-related needs of these individuals.²⁰ It has been demonstrated that anxiety and depression are significant predictors of caregiver burden in ALS. It has been demonstrated that those acting as caregivers exhibit considerable apprehension regarding the future and become increasingly critical of their role as the disease progresses.²¹ Mindfulness-based interventions can make it easier to cope with these challenges.

AIM

This scoping review aimed to evaluate and summarize the current scientific literature on the effectiveness of mindfulness-based interventions for informal caregivers of patients with ALS. It also aimed to assess the quality of evidence.

Research Questions

For this review, 5 research questions were asked:

- *"What is the effect of mindfulness-based interventions for caregivers of the patients with ALS on caregiver burden?"*
- *"What are the studies in the current literature on the subject?"*
- *"What is known about the use of mindfulness-based interventions for caregivers of the patients with ALS?"*
- *"What types of mindfulness-based interventions are used?"*
- *"What evidence is there for the acceptability and effectiveness of mindfulness-based interventions for caregivers of the patients with ALS?"*

METHODS

Study Design

A scoping review was utilized, incorporating summaries, explanations and interpretations from available quantitative, and qualitative studies to address review questions. This method allows a review to extract different data, and develop them in a way that is meaningful, transparent and systematic.²² Scoping reviews are a useful tool in the ever increasing arsenal of evidence synthesis approaches. Researchers may preference the conduct of a scoping review over a systematic review where the purpose of the review is to identify knowledge gaps, scope a body of literature, clarify concepts, investigate research conduct, or to inform a systematic review. Although conducted for different purposes compared to systematic reviews, scoping reviews still require rigorous and transparent methods in their conduct to ensure that the results are trustworthy.²³ This scoping review adhered to the PRISMA-ScR guidelines to ensure a systematic and comprehensive approach, in addition to the utilization of a scoping review methodology that was guided by the methodological framework developed by Arksey and O'Malley.²⁴

This scoping review was conducted in four steps as suggested by Arksey and O'Malley.²⁴

1. *Examining the extent, range, and nature of research*

activity.

2. *Determining the value of undertaking a full systematic review.*
3. *Summarizing and disseminating research findings.*
4. *Identifying research gaps in the existing literature.*

Types of Sources

Our search strategy primarily relied on electronic databases. Web of Science, Scopus, EBSCO, and PubMed were searched for relevant articles published by 2024. We also searched various gray literature sources, including Google Scholar, Open Grey, and PROQUEST, to capture all relevant information.

Search Strategy

Before identifying relevant articles, the authors determined keywords based on the research questions. Search terms were developed by one of the authors (L. İ.) via an iterative process, and keywords relating to ALS, mindfulness, interventions, and family caregivers. And "amyotrophic lateral sclerosis", "ALS", "motor neuron disease", "mindfulness-based stress reduction", "mindfulness", "MBSR", "mindfulness-based intervention", "caregiver burden", "caregiver stress", "caregiver fatigue", "caregiver burnout", "caregiver strain", "caregiver overload" keywords were used. In detail, the following search was conducted on Web of Science, Scopus, EBSCO, and PubMed with the following terms, as depicted in Table 1.

Table 1. In Detail the Research Conducted on Web of Science, Scopus, EBSCO, Pubmed in 2024

Electronic Databases	Search Terms
Web of Science	ALL= ((mindfulness* OR MBSR* OR "mindfulness intervention" OR "mindfulness-based stress reduction") AND ("Amyotrophic lateral sclerosis" OR "ALS" OR "motor neuron disease") AND ("caregiver burden" OR "caregiver stress"))
Scopus	"Mindfulness" AND [{amyotrophic lateral sclerosis} OR "ALS" OR {motor neuron disease}] AND [{caregiver burden} OR {caregiver stress} OR {caregiver fatigue} OR {caregiver burnout} OR {caregiver strain}]
EBSCO	- Mindfulness Based Stress Reduction OR Mindfulness OR MBSR OR Mindfulness Intervention - Motor Neuron Disease OR ALS OR MND OR Amyotrophic Lateral Sclerosis - Caregiver Burden OR Caregiver Stress OR Caregiver Fatigue OR Caregiver Burnout OR Caregiver Strain
PubMed	"mindfulness" [All Fields] AND ("amyotrophic lateral sclerosis" [MeSH Terms] OR "amyotrophic lateral sclerosis" [All Fields] OR "motor neuron disease" [All Fields]) AND "caregiver" [All Fields]

Eligibility Criteria

The inclusion and exclusion criteria were discussed among the team and established. The population, concept, and context (PCC) mnemonic for scoping reviews was used to structure the eligibility criteria.²⁵ (Table 2). The inclusion criteria for papers in this scoping review were as follows: Written in English; published in a peer-reviewed journal; employed quantitative, qualitative, or mixed-method research designs; and described a mindfulness-based intervention for caregivers of ALS patients. Data from included studies were charted and descriptively analyzed concerning the research questions. No date limitations were applied. Excluded articles that did not include mindfulness-based interventions for caregivers of the patients with ALS.

Table 2. Inclusion and Exclusion Criteria

PCC Category	Inclusion Criteria	Exclusion Criteria
<i>Population:</i> Informal Caregivers of ALS patients.	English articles Published in a peer-reviewed journal	Paid carers Not empirical research, such as case studies, editorials, or opinion pieces
<i>Concept:</i> Mindfulness Based Interventions	Employed quantitative, qualitative, or mixed-method research designs	Other types of psychological interventions, such as cognitive-behavioral therapy or relaxation techniques.
<i>Context:</i> Care of ALS patients	Mindfulness-based intervention for caregivers of ALS patients Include studies that report on outcomes relevant to caregiver well-being, such as stress, anxiety, depression, quality of life, or caregiver burden.	

Source of Evidence Selection

Firstly, the authors screened titles and abstracts, and the papers that all authors agreed on met the inclusion criteria. Each of the selected full-text papers was read thoroughly, several times by the four authors to capture all relevant information and to ensure that nothing important was missed. The dataset for the paper was constructed by extracting findings that were relevant to the research questions. The study selection process, including the number of studies identified, screened, assessed for eligibility, and included in the final analysis, is illustrated in the PRISMA flow diagram (Figure 1).

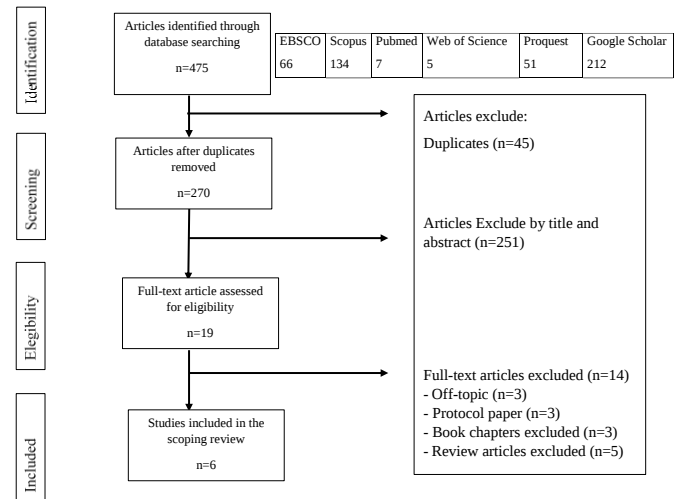


Figure 1. PRISMA Flow Diagram for Identification, Screening, Eligibility, and Inclusion

Assessment of Methodological Quality

The Downs and Black quality analysis tool was used to evaluate the quality of included studies. This tool has been shown a good intra-rater ($p=0.88$) and inter-rater (0.75) reliability and consists of 27 questions under 4 main titles: (1) unbiased reporting, (2) external validity, (3) internal validity measuring bias and confounding, and (4) power of value assessing the possibility of chance influencing the findings.²⁶ The 'power' item examines the power of the results; if there was no sample size calculation, it was scored with '0'. Contrary there was a reported sample size calculation, it was scored with '1'. Therefore, the maximum score for the randomized studies could be 28 and for the non-randomized studies could be 25.²⁷ The total score between 26 to 28 is reported as excellent; between 20 to 25 is reported as good; between 15 to 19 is reported as fair, and 14 or less is reported as poor quality.²⁸

Data Extraction

Data extraction protocols involved the following 6 stages:

- Two researchers completed the search of various sources of literature.
- Search results were screened on title/abstract by 4 researchers.
- Four researchers discussed any discrepancies and agreed.
- The selected articles were screened in full text.
- Four researchers discussed any discrepancies and agreed.
- Four researchers extracted the data.

RESULTS

As illustrated in the PRISMA flow diagram (Figure 1), a total of 475 studies were yielded by searching through databases and other sources. After screening the titles and abstracts, 19 studies remained for full-text review. Of these, 6 met the inclusion criteria and were included in the final analysis. The summaries and general information of the studies are given in Table 3 and Table 4.

The included studies were conducted in the USA (n=2)^{16,30}, Australia (n=1)¹⁹, Italy (n=1)³¹, Türkiye (n=1)²⁹ and the Netherlands (n=1).³²

The included study designs were a randomized controlled trial (RCT),³⁰ two cohort study,^{16,29} two longitudinal studies; a single group in the pre-and post-test design,^{19,31} and a qualitative study; semi-structured interviews with open-ended questionnaires (Table 3).³²

Four of the 6 studies had sample sizes of less than 30 participants. The achieved largest study sample was 114 but it was reported that decreased to 55 participants at follow-up (Table 4). No sample size limitation was set in any of included studies in this review. The participants in three of the included studies^{16,30,31} consisted of only ALS patients and their caregivers. In one of the included studies,¹⁹ the diagnosis of the patients was reported as motor neuron disease (MND) and it was mentioned that it was also known as ALS. In remaining one of the included studies consisted of only caregivers of the patients with ALS or progressive muscular atrophy (PMA) patients.³² The inclusion and exclusion criteria for each study were summarized in Table 4.

Quality of life was investigated in two studies with 36-Item Short Form Survey (SF-36),^{29,30} McGill Quality of Life Single-Item Scale (MQOL-SIS),¹⁶ and Hospital Anxiety and Depression Scale (HADS).^{16,30} The HADS was also used for assessing anxiety and depression in another study.¹⁶ Two studies assessed the caregiver burden as an outcome measure with the Zarit Burden Interview (ZBI)^{16,29,30} and one with Caregiver Reaction Assessment Scale (CRA).¹⁹ Mindfulness was assessed with Langer Mindfulness Scale (LMS) in one study,¹⁶ the Cognitive and Affective Mindfulness Scale- Revised (CAMS-R) in another study,¹⁹ and the Mindful Attention Awareness Scale in a third study.²⁹ Other outcome measures were reported as somatization, preparedness, problem-solving confidence, approach-avoidance style, and personal control.

Semi-structured interviews were conducted in two studies.^{31,32} The acceptance of intervention was assessed in one study with a specifically designed questionnaire consisting of open-ended questions asking comments from

participants on sessions and benefits.¹⁹ Both caregivers and patients participated in only one study.³⁰ In another study, the severity of physical impairment and disability related to patients were evaluated by caregivers (Table 3).³²

Four of all included studies have been focused on mindfulness-based interventions. One study has only reported assessment results without any intervention.¹⁶ One study was a RCT and compared a group of a customized online ALS Langerian mindfulness-based program (consisting of active learning, online and website-supported video, and written content about mindfulness) and wait-list controls.³⁰ One study investigated the effects of an online psychosocial support program that includes mindfulness.³² Two studies investigated face-to-face sessions of programs including mindfulness (Table 3).^{19,31}

The results of the study, which is the only RCT of all included studies, reported that the mindfulness-based program showed significant improvement in both patients and caregivers, especially in the quality of life.³³ As a result of the semi-structured interviews, the supportive meditation programs increased the awareness of caregivers and were reported effective.^{22,30} According to one study, the intervention, which focuses on caregiver self-care, problem-solving, and mindfulness and is presented in a group setting, had no significant difference in pre- and postintervention assessments. However, it has also been reported that caregivers benefit from their psychological well-being.¹⁶ However, the authors also reported that the intervention appeared to be feasible and acceptable (Table 3).¹⁹ Mindfulness was shown to be negatively correlated with burden, depression, and anxiety, and positively correlated with quality of life in a study that reported the relationship between mindfulness and health-related outcomes (Table 4).¹⁵

Table 5 presents the consensus of all four authors about the scores of the Downs&Black Analysis Tool. The quality of the included articles varied in a range of 10-20, with a total mean (standard deviation) score was 14 (3.52) (Table 5).

DISCUSSION

This paper is the first scoping review on the effects of Mindfulness-Based Interventions on caregivers of the patients with ALS and aims to provide an overall summary of the studies to collect its effect on caregivers. It was not possible to conduct a systematic review due to the limited number of published RCTs on this topic. This paper primarily discusses the effect of a mindfulness-based intervention on caregiver burden, quality of life, and psychological well-being such as anxiety and depression in caregivers of patients with ALS. Six studies were included

Table 3. Summary of Study Characteristics

Study design	Author, Year, Country	Data collection and analysis (for qualitative studies)	Intervention Sessions	Outcome Measures and Measurement times	Results, Conclusion	Feasibility and acceptability of the intervention
Longitudinal, uncontrolled, single treatment group, pre-test, post-test	Marconi, 2016, Italy ³¹	Grounded theory approach.	Adapted to ALS, the meditation program was based on the original Mindfulness-based Stress Reduction protocol. Meditation sessions were held weekly and lasted 8 weeks.	<u>Caregivers</u> Semi-structured interview were audio-recorded and transcribed verbatim. Main identified domains. 1. Improvement in well-being 2. Relaxation 3. Emotional self-regulation 4. Acceptance 5. Consciousness 6. Breathing issues 7. Sleep cycle 8. Relationships Participants attended an interview at the end of training.	Both caregivers and ALS patients reported a positive impact on their psychological well-being, promoted by an increase in acceptance and non-judgmental attitude. Furthermore, coping strategies seem to improve, with a positive effect on resilience skills. Participants also showed improvements in coping with anxiety and depression. Meditation training could be improved QoL, favored consciousness and acceptance of the disease, improved breathing and sleep quality, and favored relationships within the family and with the caregiver.	No data
	Pagnini, 2016, Italy ¹⁶	Online Questionnaire (Qualtrics survey software).	No intervention	<u>Caregivers:</u> - Mindfulness: LMS - Caregiver burden: ZBI - Quality of life: MQOL-SIS - Anxiety&Depression: HADS. Participants were assessed 2 times: 1 st ; recruitment, 2 nd ; 4 months after recruitment.	Mindfulness correlated negatively with burden, depression, and anxiety and positively with quality of life, and maintaining stability through time. People with a mindful attitude experience lower levels of burden, anxiety, and depression and report better scores of QOL compared with people with a mindless attitude. Developing a mindful attitude could well have a protective effect against burden. For that reason, interventions that promote mindfulness could increase caregivers' well-being and quality of life.	No data
Cohort study	Ipek, 2024, Türkiye ²⁹	The data were collected during these face-to-face ALS-MND Association (Antalya) visits using paper-based forms for patients and primary caregivers.	No intervention	<u>Caregivers:</u> - Mindfulness: MAAS - Caregiver burden: ZBI - Quality of life: SF-36 <u>Patients:</u> - Physical Impairment: ALSFRS-R	This study was conducted to evaluate the caregiver burden, mindfulness, and quality of life of caregivers of ALS patients. It also examined the patient's functional level and explored the relationship between these factors. In this study, the increase in the mindfulness level of the caregivers was associated with a decrease in the caregiver burden. A negative correlation was found between the caregiver burden of caregivers of ALS patients and mindfulness level and quality of life (except physical function).	No data

Table 3. Summary of Study Characteristics (Continued)

Study design	Author, Year, Country	Data collection and analysis (for qualitative studies)	Intervention Sessions	Outcome Measures and Measurement times	Results, Conclusion	Feasibility and acceptability of the intervention
A pilot study with one-arm pre- & post-test.	Ugalde, 2017, Australia ¹⁹	No relevant information could be found in the analysed study.	Single, 2.5-h group session including mindfulness, self-care, and problem-solving. 2 sessions with a 20-minute break scheduled at convenient times in 3 weeks (each participant attended once).	Caregivers: -Burden: CRA -Depression, anxiety, and somatization: BSI-18 -Preparedness: PCS -Problem-solving confidence, approach-avoidance style, and personal control: PSI -Mindfulness: CAMS-R -Acceptance of intervention: A questionnaire designed specifically for this study. Participants were assessed 3 times for acceptability (at baseline; 2-week post-intervention and 6-week post-intervention) and assessed for other outcomes 2 times (at baseline and 6-week post-intervention)	There was no significant change in outcome (distress, burden, problem-solving, mindfulness, preparedness) between pre-intervention and 6 weeks post intervention. Despite the positive feedback about the intervention in the acceptability questionnaire, this did not translate to improvements across caregiver measures.	Intervention is reported to be feasible and acceptable
	De Wit, 2019, Netherlands ³²	Semi-structured interviews were conducted by telephone using an interview guideline and audio-taped. The interview guideline was developed with open-ended questions related to caregivers' experiences with the support program in general and the specific components of the program.	A blended psychosocial support program includes mindfulness exercises The program was scheduled to be completed within 8 weeks. However, if caregivers needed more time, this could be extended to 12 weeks. The interview ranged from 38 to 82 min (m= 57 min)	Caregivers: -Severity of the patient's disability: ALSFRS-R. -Physical Impairment: SA-ALSFRS-R Behavioral changes in patients: ALS-FTD-Q Interviews were transcribed verbatim and analyzed thematically. 3 measurements completed by caregivers	The support program increased the awareness of caregivers and was evaluated effectively. Caregivers reported that the program contained all the crucial and disease-tailored themes and information. Most of the participants found the interface of the program user-friendly, the timing of the program appropriate, and flexibility in pacing themselves. The home visits of the counselor and psycho-educational information were found useful. However, caregivers reported that they did not perceive the mindfulness exercises as beneficial and did not feel the need to get in touch with peers.	No data

Table 3. Summary of Study Characteristics (Continued)

Study design	Author, Year, Country	Data collection and analysis (for qualitative studies)	Intervention Sessions	Outcome Measures and Measurement times	Results, Conclusion	Feasibility and acceptability of the intervention
A randomized controlled trial with two arms	Pagnini, 2021, Italy ³⁰	Participants received a link to a survey to be completed within 5 days via e-mail. Online using Qualtrics suite (Qualtrics, Provo,UT).	Experimental group, which participated in a customized online ALS Langerian mindfulness-based program .	<u>Caregivers:</u> -Quality of life: SF-36, HADS. -Caregiver burden: ZBI.	<u>Caregivers:</u> There was a significant time group effect for care burden, depression, anxiety , same subgroups of quality of life (role limitation due to personal or emotional problems, energy/fatigue, and emotional well-being) in the mindfulness caregiver group. No differences between groups for some subgroups of quality of life (general health perceptions, physical functioning, role limitations due to physical health problems, social functioning, and bodily pain).	Intervention is reported to be feasible and acceptable based on recruitment and anecdotal feedback from the participant.
			Two versions of the program were conducted and customized according to their physical limitations and roles for patients and caregivers.	<u>Patients:</u> -Quality of life: ALSSQOL-R, HADS. -Physical Impairment: SA-ALSFRS-R	<u>Patients:</u> There was a significant group by time effect for ALSSQOL-R, HADS Depression and Anxiety scores.	
			Online website including video and written mindfulness content and two daily exercises, (2–10 min to complete) for 5 weeks.	Participants were assessed 4 times: 1 st ; recruitment, 2 nd ; after completing intervention or 5 weeks after the recruitment, 3 rd ; 3 months after recruitment, 4 th ; 6 months after recruitment.		
Abbreviations: ALS: Amyotrophic Lateral Sclerosis; QoL: Quality of Life; LMS: Langer Mindfulness Scale; ZBI: Zarit Burden Interview; MQOL-SIS: McGill Quality of Life Single-Item Scale; HADS: Hospital Anxiety and Depression Scale; CRA: Caregiver Reaction Assessment; BSI-18: Brief Symptom Inventory; PCS: The Preparedness for Caregiving Scale; PSI: Problem-Solving Inventory; CAMS-R: Cognitive and Affective Mindfulness Scale-Revised; ALSFRS-R: Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised; ALS-FTD-Q: Amyotrophic Lateral Sclerosis-Frontotemporal Dementia-Questionnaire; SA-ALSFRS-R: Self-Administered ALS Functional Rating Scale-Revised; SF-36: Short Form 36; MAAS: Mindful Attention Awareness Scale						

Table 4. Characteristics of the Participants and Sampling in the Included Studies

First author, year	Inclusion & Exclusion Criteria	Sample size (n=baseline to the end) & drop-out rate (%)
Pagnini, 2021 ³⁰	* Caregivers: <u>Inclusion criteria</u> • Able to use a computer, and access the Internet. <u>Exclusion criteria</u> • Unsuitable for the study (determined by the clinical staff). * Patients: <u>Inclusion criteria</u> • Having the physical ability, with or without adaptive devices. • Able to use a computer and having to access Internet. • Being ≥18 years old. <u>Exclusion criteria</u> • Having frontotemporal dementia according to the Edinburgh Cognitive and Behavioral ALS Screen within 90 days of study entry. • Having significant cognitive impairment or significant uncontrolled psychiatric disease (determined by the clinical staff)	Caregivers: n=27 to 13 & 51.85% Patients: n=47 to 25 & 46.8%
Pagnini, 2016 ¹⁶	• One caregiver for each ALS patient was recruited. • The diagnosis was self-reported by subjects. • Being ≥18 years old.	Caregivers: n=114 to 55 & 51.75% Patients: n=187 to 100 & 46.52%
Ugalde, 2017 ¹⁹	• Being a caregiver of people with a diagnosis of MND within the past 12 months. • Being ≥18 years old. • Able to speak, read and write in English • Attending the neurology clinic was eligible.	Caregivers: n=15 to 13 & 13.33%
Marconi, 2016 ³¹	• Probable or defined ALS diagnosis • Diagnosis communication within 6 months of the recruitment. • Ability of the patient to speak and comprehend • Having no secondary severe comorbidity. (<i>all criteria reported only for the patients</i>)	Caregivers: n=18 & NA. Patients: n=26 & NA.
De Wit, 2019 ³²	• Being a partner of the ALS or PMA patient. • Being ≥18 years old. • Being proficient in Dutch. • Having internet access. • Having consent of the patient to participate. • Caregivers in the RCT who completed or dropped out of the support program and who finished the third measurement (approximately 6 months after baseline), were selected.	Caregivers: n=40 to 23, n=23 to 17 & 57.5% and 26.08%
Ipek, 2024 ²⁹	• Patients diagnosed with ALS and their primary caregivers. • Being ≥18 years old. • Able to communicate. • Unfamiliar with the concept of mindfulness. • Not participating in mindful meditation on their own or formal mindful meditation with a group • Not having a paid employee helping the primary caregiver.	Caregivers: n=57 & NA. Patients: n=57 & NA.

Table 5. Downs & Black Quality Analysis Tool ²⁶

Study Design	Author Country	Year	Reporting										External Validity					Bias			Internal Validity						Confounding					Power	Total Score
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28			
Non-randomized trial	Items		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28			
	Pagnini, Italy ¹⁶	2016	1	1	1	0	0	1	1	0	0	1	1	1	0*	0*	0*	1	1	1	0*	1	0*	0*	0*	0*	1	0	0	0	13		
	Marconi, Italy ³¹	2016	1	1	1	1	0	1	0	0	0	0	1	0*	0	0*	0*	1	1	1	0	1	0*	0*	0*	0	0	0*	0	10			
	De Wit, Netherlands ³²	2019	1	1	1	1	0	1	1	0	1	0	0*	1	0	0	0	1	0	1	0*	1	0*	0*	0*	0	0	0	0	1	12		
	Ugalde, Australia ¹⁹	2017	1	1	1	1	0	1	1	0	1	0	1	1	0	0	0	0	1	1	0*	1	0*	0*	0	0	0	1	0	16			
	Ipek, Türkiye ²⁹	2024	1	1	1	0	0	1	1	0	0	1	1	1	0*	0	0	1	1	1	0*	1	0*	0*	0*	0*	0*	1	0	0	13		
Randomize controlled trial	Pagnini, Italy ³⁰	2021	1	1	1	1	0	1	1	0	1	1	1	1	0	0	0	1	1	1	1	1	1	1	1	0	1	1	1	20			

Reporting: 1; Yes, 0; No. **Only for the item 5:** 2; Yes, 1; Partially, 0; No. **External Validity and Internal validity (Bias and Confounding):** 1; Yes, 0; No, 0*; Unable to determine. Power: 1; Yes, 0; No.

in this scoping review; one RCT,³⁰ two pre-post design studies,^{19,31} one qualitative study³² and two cohort study.^{16,29} The fact that studies on Mindfulness-Based Interventions for caregivers of patients with ALS have only been available since 2016, and the number of them is small, and demonstrates the lack and novelty of trials on this topic.

A review of the six included studies according to their quality levels reveals a considerable range in scores, from 10 to 20. The maximum score can be 28 for randomised trials and 25 for non-randomised trials. One study has a good quality score.³⁰ One study has an average quality score.¹⁹ The other four trials have a low quality score. It is seen that the distributions of principal confounders in each group of subjects to be compared clearly described is not performed in all studies. Not all studies reported all important adverse events that may be a consequence of the intervention. In all studies it was clear that no attempt was made to blind participants to the intervention they received. In all studies, no attempt was made to blind those measuring the main outcomes of the intervention. In all studies, the question 'Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?' was unanswered. In addition, there are very few intervention trials on the subject and very few randomised controlled trials. Therefore, the trials may not have used randomisation and blinding. This may have led to a lower quality of the trials.

The rapid progress of ALS disease makes the patient dependent on the caregiver day and night, which increases the physical and psychological burden on the caregiver, unlike other progressive chronic diseases. It is known that both the patient and the caregiver are emotionally affected by ALS.^{6,34,35} Studies are emphasizing the negative psychological effects of caregiving in ALS patients.^{36,37} It is known that negative psychological factors also increase the perceived caregiver burden³⁸ and caregivers of ALS patients need supportive interventions. One of these supportive interventions is mindfulness-based interventions, and this approach has recently been used by adapting caregivers of patients with ALS.³⁹ There is evidence that mindfulness-based interventions are feasible and acceptable for caregivers of patients with ALS.^{19,30,31}

Recently, there has been a growing interest in mindfulness-based interventions. Mindfulness-based intervention can be implemented in a variety of ways. The most known and most widely used form is the MBSR program.^{11,30} In the studies we included, the MBSR method was not used directly, but mindfulness-based programs adapted to ALS

based on the original MBSR,^{30,31} and mixed psychosocial support programs including mindfulness exercises.^{19,32} In one of the included studies, the mindfulness status of ALS caregivers was evaluated without any intervention.¹⁶

The mindfulness-based interventions have a reducing effect on the caregiver burden in various chronic diseases.^{12,33,40} Considering the positive effects of mindfulness-based interventions on caregiver burden, the number of studies that examined the effect of mindfulness-based interventions on caregivers burden in caregivers of patients with ALS in the literature was limited.^{30,31} It was reported that mindfulness-based interventions had a reducing effect on the caregiver burden^{30,31} and people with a mindful attitude had a lower level of caregiver burden than those who did not receive the mindfulness-based interventions.¹⁶ On the other hand, Ugalde et al. reported that there was no additional significant effect on caregiver burden for caregivers of patients with ALS.¹⁹ But also, developing a mindful attitude can have a protective effect against the caregiver burden,¹⁶ it is thought that mindfulness-based interventions may be important in the development of effective, efficient, sustainable, applicable, accessible and low-cost service models that reduce the caregiver burden.

Important studies emphasizing the psychological effects of caregiving in ALS patients.^{36,37} It is known that psychological factors also increase the perceived caregiver burden.^{21,38,41} There is evidence that mindfulness-based studies show significant improvement in psychological well-being.⁴⁰ Pagnini et al. assessed depression and anxiety using the HADS and they reported that the mindfulness-based intervention provides benefits for the psychological well-being of caregivers of patients with ALS. Caregivers who are more mindful will show higher psychological well-being over time.¹⁶ In a qualitative study, caregivers reported a positive impact of the mindfulness-based intervention on their psychological well-being, promoted by an increase in acceptance and non-judgmental attitude.³¹ The positive effects of mindfulness-based interventions on caregiver anxiety and depression have been demonstrated in studies conducted with various chronic patients.^{12,40,42-44} In a RCT, Pagnini et al. reported that the caregivers of patients with ALS had lower depression, anxiety, and better emotional well-being after an online non-meditative mindfulness intervention compared to the control group.³⁰ As a safe, simple, accessible and transportable approach, mindfulness-based interventions seem to improve psychological functioning and facilitate long-term self-care of caregivers.¹²

The caregivers of patients with ALS endure significant

caring pressure as a result of caring for patients with chronic illnesses, which can negatively impact their health-related quality of life.⁴⁵ There are different available non-pharmacological interventions were used for improving caregivers' health related quality of life.⁴⁶ Mindfulness based interventions seem to be an effective method in improving health-related quality of life for caregivers with different chronic diseases.^{16,30,44} Pagnini et al. examined the relationship between mindfulness and health-related quality of life in caregivers of patients with ALS, and they reported that the mindfulness-based intervention was positively related with quality of life.¹⁶ In a RCT Pagnini et al. indicated that the mindfulness-based interventions were improved the quality of life for caregivers of patients with ALS compared to control. According to current literature mindfulness-based interventions can be a beneficial approach for caregivers to have a good quality of life.

There is also a study reporting that most of the caregivers do not find mindfulness-based interventions helpful. It is to be expected that most caregivers in the study did not perceive the mindfulness exercises as helpful, reporting unpleasant reactions during the exercises, such as agitation, discomfort, or confusion. These reactions are seen as part of the psychological process. Another point to note in this study is that the caregivers who perceived the mindfulness exercises as helpful were those with previous meditation experience.³²

The findings of this scoping review revealed that the mindfulness-based interventions had a positive effect on the caregiver burden, quality of life, and psychological well-being such as anxiety and depression in caregivers of patients with ALS with limited studies. The insight of the knowledge gained through this review will add to the knowledge of interventions to reduce the burden of care for caregivers of patients with ALS.

Few studies have demonstrated the benefits of mindfulness-based interventions for caregivers of patients with ALS. Studies have significant methodological problems that render the overall evidence base low. High-quality and carefully designed research is essential for the effective implementation and testing of mindfulness-based interventions aimed at reducing the caregiver burden. Especially since the caregivers of patients with ALS are neglected and the consequences of caregiver burden can be serious, more attention should be paid to this area.

Physicians, nurses, physiotherapists, social workers, gerontologists, and all specialists who may form other members of the multidisciplinary team can suggest

structured exercises that improve a mindful attitude for caregivers.

Limitations

It is known that studies on mindfulness-based interventions are gradually increasing, and the main strength of this study is that it is the first study to examine the studies on this population and draw attention to the subject. Another one strength and contribution to the field of this study is the methodological and critical evaluation of the studies in the literature on the subject and determining the methodological development areas of future studies. We believe that this scoping review identified areas for future methodological improvement as the studies included did not meet all the criteria of the 'assessment tool we used'.

A significant limitation encountered in this scoping review was the difficulty in comparing and synthesizing the findings, given the availability of studies employing disparate methodologies and outcome measures on the topic. Notwithstanding this limitation, it is proposed that mindfulness-based practices may be an easily accessible and feasible intervention for this population, with the potential to reduce caregiver burden.

Etik Komite Onayı: Kapsam derlemesi insan denekleri, insan materyali, insan dokuları veya insan verilerini içermez. Bu nedenle etik kurul onayına gerek duyulmadı.

Hasta Onamı: Kapsam derlemesi insan denekleri, insan materyali, insan dokuları veya insan verilerini içermez. Bu nedenle hasta onamına gerek duyulmadı.

Hakem Değerlendirmesi: Dış bağımsız.

Yazar Katkıları: Fikir- Lİ; Tasarım- Lİ, GYGG; Denetleme- GYGG; Kaynaklar- Lİ; Materyaller- Lİ, PK, SBB ; Veri Toplanması ve/veya İşlemesi Lİ, SBB; Analiz ve/ veya Yorum- Lİ, GGYG, PK, SBB; Literatür Taraması- Lİ, SBB; Yazıyı Yazan- Lİ, GYGG, PK, SBB; Eleştirel İnceleme- GGYG;

Çıkar Çatışması: Yazarlar, çıkar çatışması olmadığını beyan etmiştir.

Finansal Destek: Yazarlar, bu çalışma için finansal destek almadığını beyan etmiştir.

Ethics Committee Approval: A scoping review not involves human subjects, human material, human tissues, or human data. Therefore, the approval of an ethics committee was not necessary.

Informed Consent: A scoping review not involves human subjects, human material, human tissues, or human data. Therefore, the approval of an Informed Consent was not necessary.

Peer-review: Externally peer-reviewed.

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