

REPUBLIC OF TÜRKİYE
BANDIRMA ONYEDİ EYLÜL UNIVERSITY, OFFICE OF THE RECTOR
Health Sciences Non-Interventional Research Ethics Committee

Number : E-25691463-050.04-2500036885
Subject : Asst. Prof. Dr. Zübeyde Ezgi
ERÇELİK 2025-136

16.07.2025

Dear Asst. Prof. Dr. Zübeyde Ezgi ERÇELİK
Faculty Member, Department of Pediatric Health and Diseases Nursing

AGENDA: Evaluation of the application no. 2025-136 submitted by Asst. Prof. Dr. Zübeyde Ezgi ERÇELİK

DECISION: At the meeting no. 2025-06 held by our Ethics Committee on 27.06.2025 at 10:00, the study titled "**The Effect of Buzzy and VR Used with a Vein Imaging Device in Children on Procedure Duration, Pain, Fear, and Parental Anxiety in Febrile Children**", application no. 2025-136, planned to be conducted by Meryem GELMEZ under the supervision of Asst. Prof. Dr. Zübeyde Ezgi ERÇELİK, was found ethically appropriate.

Assoc. Prof. Dr. Berna KÖKTÜRK
DALCALI
Committee Member

Assoc. Prof. Dr. Özlem PERSİL
ÖZKAN
Committee Member

Assoc. Prof. Dr. Ömer ÖZER
Committee Member

Assoc. Prof. Dr. Arzu BULUT
Committee Member

Asst. Prof. Dr. Derya AZİM
Committee Member

Asst. Prof. Dr. Canan BOZKURT
Committee Member

Prof. Dr. Yıldı Arzu ABA
Committee Chair

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Clerk

ETHICS COMMITTEE DOCUMENT

Official Title of the Study

The Effect of Buzzy and VR with Vein Imaging Device on Intervention Time, Pain, Fear,
Anxiety and Parental Anxiety in Children with Fever

ClinicalTrials.gov Identifier

Document Date: [2025-06-30]

Bandırma Onyedi Eylül University

Health Sciences Non-Interventional Research Ethics Committee



REPUBLIC OF TÜRKİYE
BANDIRMA ONYEDİ EYLÜL UNIVERSITY
HEALTH SCIENCES NON-INTERVENTIONAL RESEARCH
ETHICS COMMITTEE
APPLICATION EVALUATION FORM



INFORMATION ABOUT THE RESEARCH

1. APPLICATION TYPE	☒ New application ☐ Corrected (Revised) application
2. APPLICATION NO: (Leave blank)	E-25691463-050.04-2500036885
3. RESEARCH TITLE:	The Effect of Buzzy and VR with Vein Imaging Device on Intervention Time, Pain, Fear, Anxiety and Parental Anxiety in Children with Fever
4. PRINCIPAL INVESTIGATOR:	Assistant Professor Zübeyde Ezgi ERÇELİK, PhD
5. OTHER INVESTIGATORS:	Meryem GELMEZ, RN
6. INSTITUTION OF THE INVESTIGATOR / INVESTIGATORS	Bandırma Onyedi Eylül University Republic of Türkiye Ministry of Health Bursa Provincial Health Directorate Karacabey State Hospital
7. TYPE OF RESEARCH	☒ Thesis study ☐ Scientific research
8. NATURE OF THE RESEARCH	☒ Non-interventional research ☐ Field study ☐ Other (Please specify).....

EVALUATION CRITERIA (Leave blank)

Does the research title fall within the scope of this committee's review?	☐ Yes ☐ No ☐ Partially
Do the investigators have the qualifications and competence to conduct this study? (Are there authorization documents, etc., for special procedures?)	☐ Yes ☐ No ☐ Partially
Is the research title consistent with its content?	☐ Yes ☐ No ☐ Partially
Are the importance and rationale of the research stated?	☐ Yes ☐ No ☐ Partially
Is the purpose of the research stated?	☐ Yes ☐ No ☐ Partially
Are the units in which the research will be conducted appropriate?	☐ Yes ☐ No ☐ Partially
Is the type of sample to be used in the research appropriate for its purpose?	☐ Yes ☐ No ☐ Partially
Are the characteristics of the research sample appropriate?	☐ Yes ☐ No ☐ Partially
Are the inclusion, exclusion, or withdrawal criteria appropriate?	☐ Yes ☐ No ☐ Partially
Are the dates for collecting research data appropriate?	☐ Yes ☐ No ☐ Partially
Are the dates for conducting the research appropriate?	☐ Yes ☐ No ☐ Partially
Are the data collection tools to be used in the research appropriate?	☐ Yes ☐ No ☐ Partially
Is the data collection method appropriate?	☐ Yes ☐ No ☐ Partially
Are the methods to be used for data analysis appropriate?	☐ Yes ☐ No ☐ Partially
Have the necessary permissions been obtained for the research? (Institutional permissions, individual permissions, etc.)	☐ Yes ☐ No ☐ Partially
Has the Informed Consent Form been prepared adequately and appropriately?	☐ Yes ☐ No ☐ Partially
Does the research pose any risk of harm to participants (biological, psychological, physical, personal, etc.)?	☐ Yes ☐ No ☐ Partially
Does the research pose any environmental or institutional risk?	☐ Yes ☐ No ☐ Partially
Does the research replicate a previous study?	☐ Yes ☐ No ☐ Partially
Considering the research as a whole, are there any ethical concerns?	☐ Yes ☐ No ☐ Partially
Other comments concerning this study:	
CONCLUSION: The conduct of this study, which I have reviewed,	
☐ Has been found ethically appropriate.	☐ Falls outside the scope of the ethics committee.



REPUBLIC OF TÜRKİYE
BANDIRMA ONYEDİ EYLÜL UNIVERSITY
HEALTH SCIENCES NON-INTERVENTIONAL RESEARCH
ETHICS COMMITTEE
APPLICATION FILE CHECKLIST



☐ Requires re-evaluation after the specified corrections are made. ☐ Has not been found ethically appropriate.	☐ Requires consultation with a specialist / expert. ☐ Requires a meeting with the investigators.
ETHICS COMMITTEE MEMBER	
Full Name (Title): _____ Meeting Date: / / 20... Signature: _____	

RESEARCH TITLE: The Effect of Buzzy and VR with Vein Imaging Device on Intervention Time, Pain, Fear, Anxiety and Parental Anxiety in Children with Fever	If your answer is "No," please explain why.
1. Did you use the current application form?	☒ Yes ☐ No
2. Did you complete and sign the relevant sections of your ethics committee application petition? (Study title, Full Name, Date, and Signature)	☒ Yes ☐ No
3. Did you state the title of the research?	☒ Yes ☐ No
4. Did you provide the necessary information about the principal investigator and any other investigators?	☒ Yes ☐ No
5. Did you specify the investigators' levels of contribution?	☒ Yes ☐ No
6. Did you specify the nature of the research?	☒ Yes ☐ No
7. Did you provide the necessary information about the location(s) where the research will be conducted?	☒ Yes ☐ No
8. Did you mark the type of research?	☒ Yes ☐ No
9. Did you adequately explain the definition of the problem, the purpose, rationale, and importance of the research?	☒ Yes ☐ No
10. Did you include examples of other studies related to the research?	☒ Yes ☐ No
11. Did you provide the specified explanations regarding the materials and methods of the research?	☒ Yes ☐ No
12. Did you specify the inclusion / exclusion criteria?	☒ Yes ☐ No
13. Did you separately specify the dates for both data collection and the conduct of the research?	☒ Yes ☐ No
14. Did you list the references consulted on the subject?	☒ Yes ☐ No
15. Did you read and sign the undertaking page?	☒ Yes ☐ No
16. Did you prepare the Informed Consent Form appropriately for the research, including the necessary explanations, and attach it to the application form?	☒ Yes ☐ No
17. Did you attach the data collection tools to be used in the study to the application form?	☒ Yes ☐ No
18. Was the principal investigator's curriculum vitae attached?	☒ Yes ☐ No
19. Did you check the application form and its attachments for writing conventions, wording, clarity, font, page layout, etc.?	☒ Yes ☐ No
20. Were the relevant sections of the application form signed by all investigators?	☒ Yes ☐ No

This application file, which I have submitted to the Bandırma Onyedi Eylül University Health Sciences Non-Interventional Research Ethics Committee for evaluation, has been prepared in accordance with the rules stated above. I accept that the ethics committee will not evaluate the research if the application is submitted with incorrect or incomplete forms.

Principal Investigator

Full Name: Assistant Professor Zübeyde Ezgi ERÇELİK, PhD

BANDIRMA ONYEDİ EYLÜL UNIVERSITY
HEALTH SCIENCES NON-INTERVENTIONAL RESEARCH
TO THE CHAIR OF THE ETHICS COMMITTEE

I respectfully request that your committee evaluate the ethical appropriateness of my research entitled “The Effect of Buzzy and VR with Vein Imaging Device on Intervention Time, Pain, Fear, Anxiety and Parental Anxiety in Children with Fever.”

Assistant Professor Zübeyde Ezgi ERÇELİK, PhD

Bandırma Onyedi Eylül University

Attachments:

1. Health Sciences Non-Interventional Research Ethics Committee Application Form
2. Undertakings
3. Informed Consent Form
4. Principal investigator's curriculum vitae (in the Council of Higher Education [YÖK] format)
5. Receipt for the Ethics Committee Evaluation Fee (if required)
6. Other necessary attachments (data collection tool, certificate, etc.)
7. CD (All documents must be submitted in full as one printed copy bearing original handwritten signatures and on CD.)



REPUBLIC OF TÜRKİYE
BANDIRMA ONYEDİ EYLÜL UNIVERSITY
HEALTH SCIENCES NON-INTERVENTIONAL
RESEARCH ETHICS COMMITTEE
APPLICATION FORM



1) RESEARCH TITLE	The Effect of Buzzy and VR with Vein Imaging Device on Intervention Time, Pain, Fear, Anxiety and Parental Anxiety in Children with Fever				
2) ENGLISH TITLE	The Effect of Buzzy and VR with Vein Imaging Device on Intervention Time, Pain, Fear, Anxiety and Parental Anxiety in Children with Fever				
3) PRINCIPAL INVESTIGATOR'S					
First Name, Surname	Zübeyde Ezgi ERÇELİK				
Title / Position	Assistant Professor, PhD				
Institution / Department / Academic Division	Bandırma Onyedi Eylül University, Faculty of Health Sciences, Department of Nursing				
Area of specialization	Pediatric Nursing				
Telephone ()	Fax ()		Mobile ()		
Contact address	Bandırma Onyedi Eylül University Faculty of Health Sciences				
E-mail:	eozgen@bandirma.edu.tr		Signature		
4) OTHER INVESTIGATORS'					
First Name, Surname	Title	Institution Department / Academic Division	Area of specialization	Telephone	Signature
Meryem GELMEZ	Nurse	Republic of Türkiye Ministry of Health Bursa Provincial Health Directorate Karacabey State Hospital			
5) INVESTIGATORS' LEVELS OF CONTRIBUTION					
Type of Contribution	Description			Contributing Investigator	
Concept	Development of the research idea or hypothesis			MG, ZEE	
Design	Planning the research method			ZEE	
Supervision	Organization, oversight of the progress, and responsibility for the research			ZEE	
Provision of Resources	Literature review and provision of necessary personnel, materials, equipment, and other resources			MG	
Data Collection / Processing	Administration of questionnaires, follow-up of patients / participants, and collection and organization of data			MG	
Data Analysis	Statistical evaluation of the data			ZEE	
Reporting	Interpretation and reporting of research findings			ZEE, MG	
Critical Review	Evaluation of the research report in terms of writing conventions, language, and scientific content			ZEE	
Publication	Monitoring the publication process of the research report			ZEE, MG	

Other (if any)		
6) TYPE OF RESEARCH	☐ Scientific research for academic purposes ☐ Doctoral thesis study	☒ Master's thesis study
7) NATURE OF THE RESEARCH (More than one option may be selected depending on the nature of the research.)		
☐ Questionnaire study ☐ Observational study, such as a retrospective archive review using files and imaging records ☐ Study using collection materials from biochemistry, microbiology, pathology, and radiology, such as blood, urine, tissue, and images, or materials obtained during routine examinations and treatment procedures ☐ Cell or tissue culture study ☒ Research to be conducted within the scope of nursing activities ☐ Research related to body physiology, such as exercise ☐ Study based on anthropometric measurements ☐ Research evaluating lifestyle habits ☐ Methodological study ☐ Other (Please specify).....		
8) INSTITUTION / ORGANIZATION / CENTER WHERE RESEARCH DATA WILL BE COLLECTED	Republic of Türkiye Ministry of Health Bursa Provincial Health Directorate Karacabey State Hospital	
9) DESCRIPTION OF THE RESEARCH		
a. Purpose of the research (The statement of purpose must indicate the intended outcome of the research and must be clear, measurable, and achievable. Research questions or hypotheses, if any, must be added.) This study is planned as a randomized controlled, prospective, and cross-sectional study to evaluate the effects of a vein imaging device used with virtual reality glasses and Buzzy during peripheral intravenous catheterization (PIVC) in children aged 7–12 years presenting with fever to the Emergency Department of Karacabey State Hospital, on peripheral intravenous catheterization procedure duration, children's pain, fear, and anxiety, and parental anxiety. a.1. Research Hypotheses H0: There is no difference between groups in PIVC-related pain, fear, anxiety, procedure duration, and anxiety scores. H1a: There is a difference between groups in children's PIVC-related pain scores. H1b: There is a difference between groups in children's PIVC-related fear scores. H1c: There is a difference between groups in children's PIVC-related anxiety scores. H1d: There is a difference between groups in parents' PIVC-related anxiety scores. H1e: There is a difference between groups in PIVC-related procedure durations.		
b. Importance and rationale of the research, literature supporting this rationale, and examples of studies conducted on this subject (if any) (Must be prepared in no more than 500 words)		

During diagnosis and treatment, pediatric patients are exposed to invasive procedures such as peripheral intravenous catheterization (PIVC) that cause pain, stress, fear, and anxiety. PIVC is one of the procedures frequently used in modern medicine. This route enables many procedures, such as intravenous fluid support, continuation of medication therapy, monitoring of hemodynamic parameters, and provision of total parenteral nutrition (Eren, Topuz & Türkmen, 2020; Erdoğan and Aytekin Özdemir, 2021). However, children's narrow vessel diameter and incompletely developed vascular structures make PIVC more difficult than in adults and more likely to result in unsuccessful attempts. Particularly in units where time is critical, such as emergency departments, multiple unsuccessful attempts can prolong the procedure and cause various complications (Can and Gerçek, 2024; Demir & İnal, 2019).

Inadequate vascular access attempts can lead to negative emotional responses in children, such as pain, fear, and anxiety, as well as interruptions in treatment, tissue damage, increased need for diagnosis and treatment, and increased workload for healthcare professionals and healthcare costs. Repeated procedures also increase parental anxiety and reduce trust in healthcare services (Gümüş, 2017). Therefore, approaching children within the framework of atraumatic care should aim to reduce the duration and intensity of exposure rather than eliminate pain completely (Yurdagül, 2022).

For this purpose, non-pharmacological methods are becoming prominent, and the use of distraction tools (virtual reality glasses, Buzzy, kaleidoscopes, etc.) is becoming increasingly widespread. Because these applications are non-invasive, practical, economical, and reusable, they contribute to reducing both pain and procedure duration (Gümüş, 2019; Erdoğan and Aytekin, 2021). In particular, vein imaging devices that use infrared light to make vascular structures visible improve procedural success, reduce complications, and decrease the child's discomfort during the procedure (Gümüş, 2017).

In this context, the proposed study aims to comparatively examine the effects of distraction and technological interventions used during invasive procedures on children and parents. By integrating these methods, which have been evaluated in a limited number of studies in the literature, into nursing care, the study aims to develop evidence-based recommendations to improve patient comfort and reduce traumatic experiences.

c. Materials and methods (Provide the necessary explanations under the relevant headings according to the nature of the research)

Research type / design / model:

A randomized controlled study

Dependent and independent variables to be examined in the research:

Independent Variables: Vein imaging device, virtual reality glasses, Buzzy application

Dependent Variables: Peripheral intravenous catheterization procedure duration; the child's pain, fear, and anxiety levels during the procedure; and parents' anxiety level scores during the procedure.

Study participants—population / sample characteristics and sampling method:

The study population will consist of children presenting to the Emergency Department of Karacabey State Hospital between September 2025 and February 2026 who require vascular access, and their parents. The study sample will

consist of patients and their families who meet the inclusion criteria and are selected using stratified randomization. Stratified block randomization will be based on sex (female–male) and age (7–9 / 10–12).

Randomization

Using the G*Power statistical program for two groups, with a significance level of 0.05 and 95% power, and based on the one-way analysis of variance results used to compare mean pain scores and mean catheter insertion times in the study by Can and Gerçeker (2024) evaluating the effectiveness of a vein imaging device, it was determined that 32 participants would be required for each group. To meet the assumptions of parametric tests and allow for a 10% loss, each group is planned to include 35 children, for a total sample of 105 children.

Inclusion or exclusion criteria:

Inclusion Criteria

- Children aged 7–12 years
- Written consent indicating parents' voluntary participation in the research.
- Presence of fever ($>37.5^{\circ}\text{C}$).

Exclusion Criterion

- Parents wishing to withdraw from the study at any stage of the research
- The patient having received antipyretic and analgesic medication before the PIVC procedure.
- Presence of severe dehydration.

Dates between which research data will be collected:

Data collection is planned between September 2025 and February 2026.

Period during which the research will be conducted:

Collection is planned between September 2025 and May 2026.

The intervention / activity / process to be undertaken in the study must be described in detail.

Study groups

Vein imaging device + virtual reality glasses group: The patient and their family will be informed about the Qualmedi MT-600 Vein-Finder device to be used in the study, and it will be explained that the device is used to visualize veins. The PIVC site will be visualized using the device to identify the vein where the procedure will be performed.

Three minutes before the procedure, parents will complete the Introductory Information Form and the STAI State-Trait Anxiety Inventory, while children will complete the Wong-Baker Faces Pain Rating Scale and the Children's Fear and Anxiety Scale. The virtual reality headset will also be introduced to the child before the procedure. Sixty seconds before the procedure, the child will put on the virtual reality headset and watch the Amazon video (https://www.youtube.com/watch?v=h-O7WxpWK6A&ab_channel=ONSOUNDWAVESSOUNDDESIGN). The virtual reality headset will be removed from the child when the procedure is completed.

White “VR BOX 3.0” virtual reality glasses compatible with smartphones will be used in this study. Before the patient uses the virtual reality glasses, disposable strips will be attached to the areas that will touch the patient's face. The external surfaces and screen will be wiped with disinfectant. A child who wishes to remove the glasses during the procedure will be withdrawn from the study. The vein imaging device will be used before the vascular access procedure to visualize the patient's veins, and the nurse will select the vein based on the use of the device. The child will put on the virtual reality glasses before the vascular access procedure, and the nurse will perform the vascular access procedure immediately after the child puts on the glasses. Three minutes after the procedure, parents will complete the STAI State-Trait Anxiety Inventory, and children will complete the Wong-Baker Faces Pain Rating Scale and the Children's Fear and Anxiety Scale. The researcher will begin timing when the nurse applies the tourniquet to the child, and the procedure duration will be recorded on the form when the procedure is completed.

The primary endpoint in this group will be the patient's voluntarily wanting to remove the virtual reality glasses during the procedure. This is because a child who wishes to remove the glasses during the procedure will be withdrawn from the study. The second endpoint is the placement of vascular access and the duration of the procedure. If vascular access is successfully established, the child will be told that they may remove the virtual reality glasses. The patient's

third procedure-related endpoint is the level of procedure-related pain, fear, and anxiety, and parental anxiety, assessed 3 minutes after the vascular access procedure.

Vein imaging device + Buzzy group: The patient and their family will be informed about the Qualmedi MT-600 Vein-Finder device to be used in the study, and it will be explained that the device is used to visualize veins. The PIVC site will be visualized using the device to identify the vein where the procedure will be performed. The Buzzy® device (MMJ Labs, Atlanta, Georgia, USA) will be used in the study to reduce pain through local cold application and vibration. Buzzy combines high-frequency vibration with cold temperature and was developed to control procedural pain and redirect attention in children and adults. Measuring $8 \times 5 \times 2.5$ cm, Buzzy is a reusable plastic device that uses its battery to apply vibration and cold to the body region where it is placed. A wing-shaped ice pack is located on the part of the device that contacts the skin. The ice pack is stored in a freezer and placed on the device before use. After the application, the ice pack is wiped with 70% alcohol and kept in the freezer to refreeze. Cold application and vibration begin before the procedure and continue until its completion. Vibration reduces or eliminates pain by causing numbness, paresthesia, and anesthesia (Erdoğan and Aytakin Özdemir, 2021).

Three minutes before the procedure, parents will complete the Introductory Information Form and the STAI State-Trait Anxiety Inventory, while children will complete the Wong-Baker Faces Pain Rating Scale and the Children's Fear and Anxiety Scale. For children in this group, the Buzzy device will be placed at the procedure site (antecubital fossa) 60 seconds before blood collection begins, and cold and vibration will be started. At the end of this period, the nurse will move the Buzzy device approximately 3 cm above the procedure site, secure the tourniquet, and perform the procedure. Buzzy application will continue throughout the procedure, and the device will be removed when the procedure is completed. Three minutes after blood collection, parents will complete the STAI State-Trait Anxiety Inventory, and children will complete the Wong-Baker Faces Pain Rating Scale and the Children's Fear and Anxiety Scale. The researcher will begin timing when the nurse applies the tourniquet to the child, and the procedure duration will be recorded on the form when the procedure is completed.

The primary endpoint in this group will be the patient's not wanting the Buzzy application. In this case, the child will be withdrawn from the study. The second endpoint is the placement of vascular access and the duration of the procedure. If vascular access is successfully established, the Buzzy device will be removed. The patient's third procedure-related endpoint is the level of procedure-related pain, fear, and anxiety, and parental anxiety, assessed 3 minutes after the vascular access procedure.

Vein imaging group: In the vein imaging group, a vein imaging device will be used during PIVC in addition to the standard procedure. Three minutes before and 3 minutes after the procedure, parents will be asked to complete the STAI State-Trait Anxiety Inventory, and children will be asked to complete the Wong-Baker Faces Pain Rating Scale and the Children's Fear and Anxiety Scale. The researcher will begin timing when the nurse applies the tourniquet to the child, and the procedure duration will be recorded on the form when the procedure is completed. The primary endpoint in the vein imaging group is the placement of vascular access and the duration of the procedure. The second endpoint is the level of procedure-related pain, fear, and anxiety assessed 3 minutes after the vascular access procedure.

Data collection tools [Descriptions of the data collection tools and the validity and reliability information for the scales used must be provided with appropriate citations] (The data collection tools used must be attached):

Data Collection Tools

The Introductory Information Form, Wong-Baker Faces Pain Rating Scale, Children's Fear and Anxiety Scale, and STAI State-Trait Anxiety Inventory to measure parental anxiety will be used in the research, and data will be collected taking Procedure Duration into account.

Introductory Information Form

The Introductory Information Form consists of questions concerning the sociodemographic characteristics of the children participating in the study and the procedure duration. Sociodemographic characteristics include the child's "age and sex." The form includes the parent's relationship to the child, age, and educational status.

Wong-Baker Faces Pain Rating Scale

The Wong-Baker Faces Pain Rating Scale used to assess pain in this research was originally developed by Donna Wong and Connie Morain Baker in 1981 and revised in 1983. It is a visual measurement tool widely used worldwide to assess pain levels in children aged three years and older and allows children to express themselves through facial expressions. The scale contains six different facial expressions: the smiling face on the far left represents no pain with a score of 0, while the crying face on the far right represents severe pain with a score of 10. When administering the scale, the meaning of each face is explained to the child, who is asked to select the facial expression that best represents how they feel. The scale has frequently been used in similar studies previously conducted in Türkiye (Erdoğan and Aytakin Özdemir, 2021; Gerçeker et al., 2018). An e-mail will be sent through the official Wong-Baker Faces

Foundation website to request permission to use the scale, and the Turkish version of the scale and permission for its use have been obtained from the Wong-Baker Faces Foundation.

Children's Fear and Anxiety Scale (ÇKAÖ)

Developed by McMurtry and colleagues in 2011, this scale was designed to assess children's fear and anxiety levels. Its Turkish validity and reliability were established by Gerçekler et al. (2018). The scale is administered by presenting children with an image containing five different facial expressions rated from 0 to 4. Each facial expression represents a particular emotional state. Researchers or parents may administer the scale to determine fear and anxiety levels both before and during the procedure. A score of “0” indicates that the child experiences no fear or anxiety, while “4” represents the highest level of fear and anxiety (Gerçekler et al., 2018; Akdemir, 2019; Akan, 2024). Because the Children's Fear and Anxiety Scale uses a scoring format, item-total correlation and Cronbach's alpha coefficient could not be calculated.

STAI State-Trait Anxiety Inventory

The scale was developed by Spielberger and colleagues (1970) to assess individuals' anxiety levels both at a particular moment (state) and as a persistent characteristic (trait). Its Turkish adaptation and validity and reliability study were conducted by Öner and Le Compte (1998). The scale consists of two subscales, trait and state, each containing 20 questions. The state anxiety scale determines how individuals feel at a specific moment and under specific conditions, while the trait anxiety scale determines how individuals feel independently of their current situation and conditions. Participants provide a four-point Likert-type response to each item (not at all, somewhat, very much, completely). Scores obtained from the inventory range from 20 to 80; higher scores indicate higher anxiety levels, and lower scores indicate lower anxiety levels (Firat, 2016; Kaçmaz, 2024). In classifying STAI state and trait anxiety scores, scores below 36 are classified as “no anxiety,” scores of 37–42 as “mild anxiety,” and scores of 42 and above as “high anxiety” (Yurdaor et al., 2022). The internal consistency (item homogeneity) and reliability of the Turkish-adapted scales were determined using Kuder–Richardson 20, item-remainder correlations, and the test–retest technique. The Kuder–Richardson (alpha) reliability coefficients were found to range from 0.83 to 0.87 for the Trait Anxiety Scale and from 0.94 to 0.96 for the State Anxiety Scale. Item-remainder reliability correlations range from 0.34 to 0.72 for the Trait Anxiety Scale and from 0.42 to 0.85 for the State Anxiety Scale. Test–retest reliability coefficients were shown to range from 0.71 to 0.86 for the Trait Anxiety Scale and from 0.26 to 0.68 for the State Anxiety Scale. In this research, the state subscale of the STAI will be used to assess parents' anxiety levels. This scale is a measurement tool with established validity and reliability, widely used in healthcare, particularly to determine the immediate anxiety experienced by families during medical procedures involving children (Firat, 2016; Kaçmaz, 2024; Yurdaor et al., 2022).

Data collection method (If the principal investigator must hold a specific authorization document [certificate, etc.] to conduct the research, it must be attached to the application form).

The patients to be included in this study will be pediatric patients presenting to the Emergency Department of Karacabey State Hospital. When a physician requests vascular access, methods will be applied before vascular access is established in children who meet the inclusion / exclusion criteria, to improve procedural success and distract the child. These methods are the use of a vein imaging device with virtual reality glasses and the use of a vein imaging device with Buzzy. There will also be a patient group in which only the vein imaging device is used.

The vein imaging device falls within the scope of medical devices and will be registered in the Product Tracking System (ÜTS). Virtual reality glasses and Buzzy will be used to distract the child and increase procedural success by preventing movement of the procedure site. Virtual reality glasses and Buzzy do not fall within the scope of medical devices. All these applications will be used on pediatric patients before and during the vascular access procedure.

Parents of children who meet the inclusion criteria will be informed about the study, and children whose parents agree to participate will be included. Parents will be told that PIVC is a routine procedure, that a nurse will perform PIVC, and that a researcher will record the data obtained.

Method of data analysis:

Statistical analyses will be performed using the IBM SPSS Statistics 22.0 software package (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.). G*Power will be used for power analysis. In evaluating the data, counts, percentages, means, and standard deviations will be used as descriptive statistics. Whether the data follow a normal distribution will be tested using the Shapiro–Wilk analysis. For numerical variables that do not follow a normal distribution, the Wilcoxon test, a non-parametric test, will be used. For numerical variables that follow a normal distribution, the paired t-test, a parametric test, will be used.

Limitations of the research:

The most important limitation of the research is that it will be conducted at a single center and that its results can be generalized to its own population.

Ethical principles:

The necessary ethics committee approval and institutional permission from Karacabey State Hospital, where the study will be conducted, will be obtained, along with verbal consent from the children included in the research and written and verbal consent from their parents. Data collection will begin after the necessary permission and approval process. Participants will be informed that the data obtained from the research will be used solely for research purposes and that they have the right to withdraw at any time. The principles of Helsinki will be followed.

d. Reference List (Use APA style).

- Akan, Z. (2024). The effect of active distraction methods used during venous blood collection in children on pain and fear: Whistle blowing and bubble blowing (Published master's thesis). Atatürk University, Erzurum.
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UNDERTAKING

To the Chair of the Bandırma Onyedi Eylül University Health Sciences Non-Interventional Research Ethics Committee, concerning the research entitled “The Effect of Buzzy and VR with Vein Imaging Device on Intervention Time, Pain, Fear, Anxiety and Parental Anxiety in Children with Fever”:

1. GOOD CLINICAL PRACTICE UNDERTAKING

We undertake to comply throughout the research with the World Medical Association (WMA) Declaration of HELSINKI and/or the World Psychiatric Association Declaration of HAWAII and the rules of Good Clinical Practice, and to immediately notify your ethics committee in writing in the event of an unexpected adverse effect or event, a need to amend the study protocol during the research, or discontinuation of the research.

2. UNDERTAKING REGARDING THE ABSENCE OF CONFLICTS OF INTEREST

We declare that, during the planning, conduct, reporting, and publication of the research, we have no commercial, political, or personal connections with the organizations funding the research or with the places and persons where and with whom the research will be conducted that could harm its scientific and ethical integrity.

3. FINANCIAL UNDERTAKING

We accept that financial responsibility for research expenses rests with the investigators and undertake not to use social security institutions or revolving funds as sources of financing.

4. UNDERTAKING TO OBTAIN APPROVAL FROM THE INSTITUTION WHERE THE RESEARCH WILL BE CONDUCTED

We undertake to obtain the necessary research permission from the institution where the research will be conducted within no more than 6 months and submit it to your committee.

5. UNDERTAKING TO PROVIDE INFORMATION ABOUT RESEARCH RESULTS

We undertake to submit a report to your committee when the research is completed and converted into an academic publication.

6. UNDERTAKING TO ENSURE THE CONFIDENTIALITY OF DATA OBTAINED IN THE RESEARCH

We undertake to keep patients' / individuals' information confidential, not to share the data obtained with third parties, and to accept all legal responsibility arising in this regard.

7. UNDERTAKING THAT THE RESEARCH HAS NOT STARTED

We undertake that the research has not previously been conducted or initiated by us.

8. UNDERTAKING THAT THE APPLICATION INFORMATION IS CORRECT

We undertake that all information declared in the ethics committee application form concerning the research (information about investigators, investigators' signatures, information about the research process, etc.) is correct.

Principal Investigator / Other Investigators' First Name, Surname

Signature

Principal Investigator / Other Investigators' First Name, Surname

Signature

Assistant Professor Zübeyde Ezgi ERÇELİK, PhD

Meryem GELMEZ, RN



INFORMED CONSENT FORM

... / ... /

INTERVENTION GROUP (Buzzy + Vein Imaging)

Dear Participant,

We invite you to participate in the research entitled “The Effect of Buzzy and VR with Vein Imaging Device on Intervention Time, Pain, Fear, Anxiety and Parental Anxiety in Children with Fever,” conducted by Assistant Professor Z. Ezgi ERÇELİK, PhD, a faculty member at Bandırma Onyedi Eylül University Faculty of Health Sciences, and Meryem GELMEZ, RN. Before deciding whether to participate, you need to know why and how this research will be conducted. Please ask us if there is anything you do not understand or that is unclear to you, or if you would like further information.

Participation in this study is entirely voluntary. You have the right not to participate or to withdraw at any time after joining the study. Responding to the study will be interpreted as your consent to participate in the research. Do not feel pressured by anyone when answering the questions in the forms provided to you. Personal information obtained from these forms will be kept completely confidential and used solely for research purposes.

Purpose of the Study

The purpose of this study is to comparatively examine the effects on children and parents of distraction and technological interventions used during invasive procedures.

Procedures

If you wish to participate voluntarily in this research, 3 minutes before the procedure parents will complete the Introductory Information Form and the STAI State-Trait Anxiety Inventory, while children will complete the Wong-Baker Faces Pain Rating Scale and the Children's Fear and Anxiety Scale. After the forms are completed, Buzzy will be applied, and the vascular access site will be identified using the vein imaging device. Three minutes after PIVC, parents will be asked to complete the STAI State-Trait Anxiety Inventory, and children will be asked to complete the Wong-Baker Faces Pain Rating Scale and the Children's Fear and Anxiety Scale. After the nurse applies the tourniquet, the researcher will time the procedure in minutes and record it on the form. This research poses no risk / harm to you.

Confidentiality

The data collection tool contains no personal questions. Your answers will not be shared with anyone, and the research results will be used solely for scientific purposes. If necessary, the investigator conducting the research and ethics committee members may access your information in this study. You may also access your own information at any time.

Participation and Withdrawal

Participation in this research is entirely voluntary. You have the right not to participate or to withdraw at any time after joining without being subject to any penalty. The principal investigator may also exclude you from the research if deemed necessary. If you participate, you will not be charged any fee, and you will receive no payment.

Contact Persons

If you have any questions or concerns about the study, you may contact the researcher, Meryem GELMEZ, at 05456988304. I have read the above text that must be provided to the volunteer before the research. Written and verbal explanations have been given to me concerning this information. Under these conditions, I agree to participate in this research of my own free will, without any pressure or coercion.

I have read the above text that must be provided to the volunteer before the research. Written and verbal explanations have been given to me concerning this information. Under these conditions, I agree to participate in this research of my own free will, without any pressure or coercion.

For persons under parental custody or guardianship

Parent / Guardian's First Name – Surname:

Signature:

Address (telephone no., fax no., if any):

Investigator Providing the Explanations

First Name – Surname: Meryem GELMEZ

Signature:



INFORMED CONSENT FORM

... / ... /

INTERVENTION GROUP (Vein Imaging + Virtual Reality Glasses)

Dear Participant,

We invite you to participate in the research entitled “The Effect of Buzzy and VR with Vein Imaging Device on Intervention Time, Pain, Fear, Anxiety and Parental Anxiety in Children with Fever,” conducted by Assistant Professor Z. Ezgi ERÇELİK, PhD, a faculty member at Bandırma Onyedi Eylül University Faculty of Health Sciences, and Meryem GELMEZ, RN. Before deciding whether to participate, you need to know why and how this research will be conducted. Please ask us if there is anything you do not understand or that is unclear to you, or if you would like further information.

Participation in this study is entirely voluntary. You have the right not to participate or to withdraw at any time after joining the study. Responding to the study will be interpreted as your consent to participate in the research. Do not feel pressured by anyone when answering the questions in the forms provided to you. Personal information obtained from these forms will be kept completely confidential and used solely for research purposes.

Purpose of the Study

The purpose of this study is to comparatively examine the effects on children and parents of distraction and technological interventions used during invasive procedures.

Procedures

If you wish to participate voluntarily in this research, 3 minutes before the procedure parents will complete the Introductory Information Form and the STAI State-Trait Anxiety Inventory, while children will complete the Wong-Baker Faces Pain Rating Scale and the Children's Fear and Anxiety Scale. After the forms are completed, the virtual reality glasses will be put on, and the vascular access site will be identified using the vein imaging device. After the groups have been determined, the vein imaging device, Buzzy, and virtual reality glasses will be used during PIVC. Three minutes after PIVC, parents will be asked to complete the STAI State-Trait Anxiety Inventory, and children will be asked to complete the Wong-Baker Faces Pain Rating Scale and the Children's Fear and Anxiety Scale. After the nurse applies the tourniquet, the researcher will time the procedure in minutes and record it on the form. This research poses no risk / harm to you.

Confidentiality

The data collection tool contains no personal questions. Your answers will not be shared with anyone, and the research results will be used solely for scientific purposes. If necessary, the investigator conducting the research and ethics committee members may access your information in this study. You may also access your own information at any time.

Participation and Withdrawal

Participation in this research is entirely voluntary. You have the right not to participate or to withdraw at any time after joining without being subject to any penalty. The principal investigator may also exclude you from the research if deemed necessary. If you participate, you will not be charged any fee, and you will receive no payment.

Contact Persons

If you have any questions or concerns about the study, you may contact the researcher, Meryem GELMEZ, at. I have read the above text that must be provided to the volunteer before the research. Written and verbal explanations have been given to me concerning this information. Under these conditions, I agree to participate in this research of my own free will, without any pressure or coercion.

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For persons under parental custody or guardianship

Parent / Guardian's First Name – Surname:

Signature:

Address (telephone no., fax no., if any):

Investigator Providing the Explanations

First Name – Surname: Meryem GELMEZ

Signature:



INFORMED CONSENT FORM

... / ... /

CONTROL GROUP

Dear Participant,

We invite you to participate in the research entitled “The Effect of Buzzy and VR with Vein Imaging Device on Intervention Time, Pain, Fear, Anxiety and Parental Anxiety in Children with Fever,” conducted by Assistant Professor Z. Ezgi ERÇELİK, PhD, a faculty member at Bandırma Onyedi Eylül University Faculty of Health Sciences, and Meryem GELMEZ, RN. Before deciding whether to participate, you need to know why and how this research will be conducted. Please ask us if there is anything you do not understand or that is unclear to you, or if you would like further information.

Participation in this study is entirely voluntary. You have the right not to participate or to withdraw at any time after joining the study. Responding to the study will be interpreted as your consent to participate in the research. Do not feel pressured or influenced by anyone when answering the questions in the forms provided to you. Personal information obtained from these forms will be kept completely confidential and used solely for research purposes.

Purpose of the Study

The purpose of this study is to comparatively examine the effects on children and parents of distraction and technological interventions used during invasive procedures.

Procedures

If you wish to participate voluntarily in this research, venous access will be performed for you and your child using a vein imaging device in addition to standard hospital procedures. Three minutes before the procedure, parents will complete the Introductory Information Form and the STAI State-Trait Anxiety Inventory, while children will complete the Wong-Baker Faces Pain Rating Scale and the Children's Fear and Anxiety Scale. Three minutes after the procedure, parents will be asked to complete the STAI State-Trait Anxiety Inventory, and children will be asked to complete the Wong-Baker Faces Pain Rating Scale and the Children's Fear and Anxiety Scale.

Benefits and Risks of the Study

This research poses no risk / harm to you.

Confidentiality

The data collection tool contains no personal questions. Your answers will not be shared with anyone, and the research results will be used solely for scientific purposes. If necessary, the investigator conducting the research and ethics committee members may access your information in this study. You may also access your own information at any time.

Participation and Withdrawal

Participation in this research is entirely voluntary. You have the right not to participate or to withdraw at any time after joining without being subject to any penalty. The principal investigator may also exclude you from the research if deemed necessary. If you participate, you will not be charged any fee, and you will receive no payment.

Contact Persons

If you have any questions or concerns about the study, you may contact the researcher, Meryem GELMEZ, at I have read the above text that must be provided to the volunteer before the research. Written and verbal explanations have been given to me concerning this information. Under these conditions, I agree to participate in this research of my own free will, without any pressure or coercion.

Parent / Guardian's First Name – Surname:	Investigator Providing the Explanations
Signature:	First Name – Surname: Meryem GELMEZ
Address (telephone no., fax no., if any):	Signature:
Date:	