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RESEARCH ARTICLE

The Effect of Tens on Pain and Fear in Children with Abdominal Surgery: A Randomized Controlled Trial Protocol

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ABSTRACT

This This study is the protocol of a randomized controlled trial. The protocol is designed according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT). The study, which was aimed to reach 44 children, was completed with 50 children (aged 7-12) who had abdominal surgery. Children were randomized into experimental and control groups. The intervention group received a 40-minutes session of TENS before mobilization, while the control group received no intervention. The study was planned to be implemented between July 2021 and November 2022. Data were collected using a personal information form, the Wong-Baker FACES Pain Rating Scale (WB-FACES), the Visual Analog Scale (VAS), and the Children's Fear Scale (CFS). It is important to manage pain in pediatric patients in the postoperative period. However, there is little evidence suggesting the effectiveness of nonpharmacologic methods. Moreover, there is limited research investigating the effect of TENS on pain during mobilization. Some patients experience delayed mobilization because they cannot manage pain in the postoperative period. Delayed mobilization causes complications. Therefore, it is important to manage pain effectively. Our results indicate that TENS helps children with abdominal surgery mobilize earlier in the postoperative period. Children and parents participating in the study assisted and contributed to the researchers in the data collection process.

Research: This was a randomized controlled trial registered on ClinicalTrials.gov (ref. no: NCT 05119621).

Contents

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1. Introduction

Pain due to any trauma, disease or various procedural interventions, postoperative process is one of the most common unwanted experiences experienced by children and can often be ignored [1]. It is recommended to be considered as a vital sign [2]. Pain is a complex experience, the experience of which is influenced by many factors and usually occurs in children with non-chronic acute-onset diseases such as injury, trauma, burns, wound debridement, dressing, vaccination, vascular access, lumbar puncture. It is also very common in the post-operative period. It also occurs in children due to chronic diseases such as sickle cell anemia, cancer and asthma [3, 4]. From a clinical point of view, this condition, which is frequently seen, is a symptom that needs to be evaluated and managed very well. Ineffective management of pain does not only affect the child. It also negatively affects the adaptation of the family to the process and leads to increased anxiety and various somatic symptoms [5].

Although there are many factors that affect the response of children to pain, pain creates a response to physiological stress in the child. It causes significant changes in the child's many organ systems such as cardiovascular, respiratory, renal, musculoskeletal and immune systems [3, 5]. Although the side effects of post-operative pain, which is one of the most common acute pains, on the child are known, especially in children in this period, the routine analgesic procedure of the clinic is not too much. Effective application of existing knowledge about pain in children often results in children experiencing pain for longer than expected [6]. It is the right of every child to live a pain-free life and it would be beneficial for health professionals to step out of their routine and consider non-pharmacological methods in addition to pharmacological methods in pain management [2, 4].

Providing the child with a comfort zone, which is included in the philosophy of pediatric nursing, reduces the pain, increases the quality of care, and allows the child to recover faster in the postoperative period. Studies on TENS are quite old and no studies have been found on children in the 7-12 age groups [7, 8]. Although there are many pain management methods in pediatric patients, TENS appears to have been addressed in limited studies. This study is aimed to evaluate the effect of TENS application on pain and stress level in post-operative children.

2. Material and Method

2.1. Design

This protocol adopted a single-center, single-blind, parallel design randomized controlled design. Children who underwent abdominal surgery in the pediatric surgery clinic of a medical Selçuk University hospital in Konya were randomized in experimental and control groups (1:1). The study followed the Standard Protocol Items: Recommendations for Interventional Trials SPIRIT [9] and Consolidated Standards of Reporting Trials (CONSORT) [9].

Table 1 shows the EQUATOR Network reporting guidelines. Study was registered on Clinical Trials. The data were collected between July 2021 and November 2022. The data were analyzed and reported in March 2023.

2.2. Inclusion Criteria

- Being 7 to 12 years of age
- Having an indication for abdominal surgery (appendicitis or inguinal surgery)
- Volunteering.

2.3. Exclusion Criteria

- Undergoing analgesia treatment,
- Difficult to mobilize
- Having developed complications during surgery.

2.4. Termination Criteria

No evidence suggests that TENS is harmful. However, children were allowed to withdraw from study at any time. Moreover, children were excluded in case of a complication.

Table 1 SPIRIT figures with design and outcome assessment

	Enrolment	Baseline (T_0)	Intervention	Follow-up		
TIME POINT	After diagnosis (T_{-1})	Before the first intervention (T_0)	TENS Procedure	Beginning of the procedure (T1)	During the procedure (T2)	The 30th minute after the TENS procedure (T3)
ENROLMENT						
Eligibility screen	*					
Informed consent	*					
Randomization		*				
INTERVENTIONS						
Intervention			*			
Control						
ASSESSMENTS						
Demographics		*		*	*	*
VAS		*		*	*	*
CFS		*		*	*	*
WB-FACES		*		*	*	*

2.5. Population and Sample

The study population consisted of all pediatric patients who underwent abdominal surgery (divided into two layers; appendicitis surgery and inguinal region surgery). The sample consisted of 50 participants. A power analysis was used to determine the sample size based on Fiorelli et al., [10] (G*Power 3,1). The results showed that a sample of 40 would be enough to detect significant differences (1.1 effect size, 0,05 margin of error, and 0,95 power). However, we recruited 50 patients to avoid missing data.

2.6. Randomization

Permutation was used for a balanced distribution between groups. Block sets were generated for each combination of the identified variables. Stratified randomization was used to ensure homogeneity in the characteristics of children in each stratum.

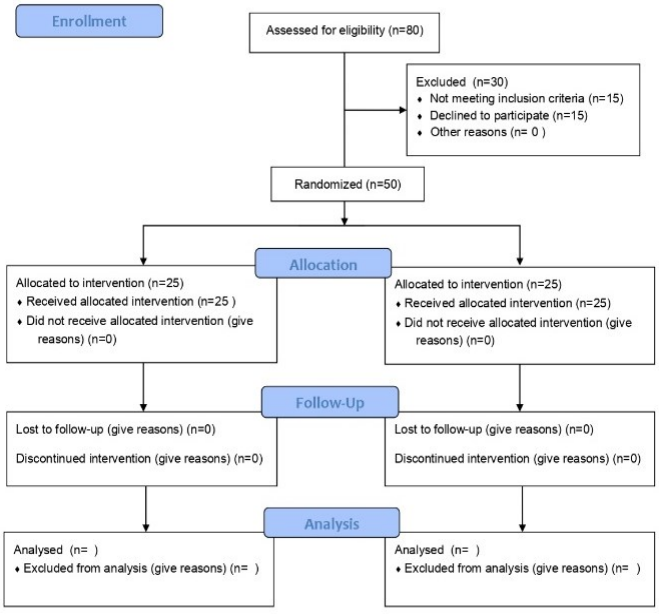

Figure 1 CONSORT 2010 Flow Diagram

This process provided data reliability. A random sample without stratification may cause undesirable situations. Therefore, we used stratified sampling by type of abdominal surgery (by abdominal surgeries) for randomization. For equal distribution, we developed two strata: appendicitis and inguinal surgeries (ovarian and abdominal cyst removal, orchiopexy, cystoscopy). Permutation was used for balanced strata.

The block sets were generated by a statistician (independent of the study) for each combination of prognostic factors (according to abdominal surgery). The groups were determined by lot. Combinations including A and B (A= control group and B= TENS experimental group) were formed. The randomization table was kept from the researchers until the intervention started. Forty-four sealed envelopes were given to an independent clinic nurse, who gave them back to the researcher in the order of randomization. The researcher opened them one by one. The researcher learned the group assignment before the intervention (Figure 1).

2.7. Data Collection Tools

The WB-FACES, VAS, CFS, and personal information forms were used to collect the data.

2.7.1. Personal information form

This form was based on review of a literature conducted by the researchers. This form's items are; age, gender, parents' age, education, family type, and income and surgery-related characteristics patient's complaints, type of surgery, previous operation experience, etc. [10, 11]. Three experts (two academics in pediatric nursing and one pediatric surgeon) were consulted for intelligibility and relevance.

2.7.2. Wong-Baker Faces Pain Rating Scale

Wong and Baker created the Wong-Baker Faces Pain Rating Scale (WB-FACES) in 1981, and it was revised in 1983 [12]. It consists of six faces with various expressions, each one denoting a progressively worsening level of pain from left (0) to right (5). Higher scores reflect a low pain threshold [12, 13].

2.7.3. Visual analog scale (VAS)

The Scale is employed to gauge the severity of pain. The measuring tool consists of a horizontal or vertical line that is 10 cm or 100 mm long, with anchor statements "no pain" or "pain at its least" at the leftmost end and "unbearable pain" or "worst pain imaginable" at the rightmost end. The distance in centimeters between the mark and the left end of the line is used to calculate the VAS score. For pediatric patients over the age of six, the VAS is an easy to use and understand scale [11, 14].

2.7.4. Children's fear scale (CFS)

The Scale was developed by McKinley et al., [15]and adapted to Turkish by Gerçeker et al. [16]. The instrument assesses pain and anxiety in pediatric patients before and after surgery. Parents and researchers can also fill out the instrument.

2.8. Data Collection

The researchers briefed all parents about the research purpose and procedure and obtained written and verbal consent from those who agreed to have their children participate in the study. The researchers also obtained verbal consent from all children.

2.8.1. Experimental group

The researcher conducted a face to face interview with each experimental group participant and filled out the personal information form in the participant's room before mobilization. Afterward, the researcher, participant, and parent evaluated the CFS and the WB-FACES Pain Rating Scale separately. The researcher asked the participant to indicate their pain level on the VAS. Then, the researcher implemented a 40-minute session of TENS (intervention). Thirty minutes after the intervention, the researcher, participant, and parent evaluated the CFS and The WB-FACES Pain Rating Scale separately. The researcher asked the participant to indicate their pain level on the Visual Analog Scale. The participant was then mobilized. Thirty minutes after mobilization, the researcher, participant, and parent evaluated the CFS and the WB-FACES Pain Rating Scale separately. The researcher asked the participant to indicate their pain level on the Visual Analog Scale. All in all, the scales were administered three times: at the beginning of the intervention, during the intervention, and 30 minutes after the implementation. Before starting the study, written and verbal consent was obtained from the parents and verbal consent from the children.

2.8.2. Control group

The control group received no intervention other than routine practice. The researcher conducted a face-to-face interview with each control group participant and filled out the personal information form in the participant's room before mobilization. Afterward, the researcher, participant, and parent evaluated the CFS and the WB-FACES Pain Rating Scale separately. The researcher then asked the participant to indicate their pain level on the VAS. The researcher permitted the control group participants who wanted to receive TENS after data collection

2.9. Intervention

A dual-channel four-electrode Compex 3 brand TENS device was used. It is important that the child is conscious and communicates with the researcher to provide stimulation so that the patient does not feel uncomfortable during TENS. Before the procedure, the patient and his/her parents were informed about TENS. Two electrodes were placed two cm to the right of the incision site, and the other two electrodes were placed two cm to the left of the incision (Figure 1). TENS had a frequency, pulse width, and duration of 100 Hz, 140 μs, and 40 minutes, respectively. Both groups received routine analgesic treatment. The experimental group participants received TENS one hour after pain relief treatment (Table 2).

Table 2 Detail and timing data collection

Measure	Demographics	VAS	CFS	WB-FACES
T_0	*	*	*	*
T_1		*	*	*
T_2		*	*	*
T_3		*	*	*

T_0: Before first intervention; T_1: Beginning of the procedure T_2: During the procedure; T_3: 30th minute after the TENS procedure

2.10. Ethical Considerations

This study was reported according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT, 2013) [17]. Study was approved by the Turkish Medicines and Medical Devices Agency (E: 68869993-511.06-427307). Written consent was received from parents, while verbal consent was received from all participants.

2.11. Data Analysis

The data will be analyzed using the Statistical Packages for Social Sciences (IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.). Descriptive statistics [mean, median, standard deviation, interquartile range (IQR), number, and percentile] will be used for categorical and continuous variables. The homogeneity of variances will be analyzed using the "Levene" test. One-way Analysis of Variance will be used for comparisons of three or more independent groups, while repeated measures Analysis of Variance and Bonferroni's multiple comparison test will be used for comparisons of three or more dependent groups. Using Fisher's Exact and Chi-Square tests, the relationships between categorical variables will be examined. Normality will be tested using the Shapiro-Wilk test. For repeated tests, the assumption of sphericity was checked with the Mauchly test, and the sphericity Assumed test will be applied if the assumption of sphericity is met, and if not, the results of the Huynh-Feldt test will be evaluated for cases where the epsilon value is greater than 0.75 and the Greenhouse Geisser test for cases where it is smaller. The Bonferroni-Dunn test will be used in within times with regard to clinical parameters and patient groups.

2.12. Declaration of Helsinki

The Declaration of Helsinki requires informed consent from parents and children in randomized controlled trials. We will obtain informed consent from children and their parents who agree to participate in the study. Selcuk University ethics committee has approved the research (E-40209705-050.01.04-52829). Approval was received from the Turkish

Medicines and Medical Devices Agency in addition to the ethics committee approval for the study (E-68869993-511.06-427307).

2.13. Trial Organization

Coordination Group: The coordinating center is the Faculty of Medicine and the Faculty of Nursing, at Selçuk University. The coordination group is personally responsible for the design of the research and all phases of the daily management of the research. The Coordination Group of the Study is also responsible for preparing and presenting reports to the Steering Committee.

2.14. Data Monitoring Committee

The intervention method used in the study is a non-pharmacological intervention that is unlikely to have side effects. The committee will oversee the progress of the study but the study may take 11-12 months. An independent DMC will therefore monitor the results. The Turkish Medicines and Medical Devices Agency is authorized to conduct data audits when necessary.

2.15. Current Status of the Study

At the time that this document was submitted, data collection was finished, but data analysis and reporting is still ongoing.

2.16. Dissemination of study outcomes

The findings might be presented at the convention and published in a peer-reviewed journal.

3. Discussion

Early mobilization after abdominal surgery is critical. Minimal pain is also necessary for early mobilization. Postoperative pain management aims to ensure that the patient can be mobilized early and thus minimize postoperative complications. Thus, the patient will stay in the hospital less, contributing to the national economy by minimizing costs. Many treatment methods inhibit pain in the postoperative period [11, 18]. TENS is one of the techniques used to treat pain after surgery. TENS is an electrophysiologic agent that noninvasively reduces acute or chronic pain by stimulating peripheral nerves [19, 20]. Some researchers have investigated the effect of TENS on pain after abdominal surgery in adults but there is no data on the effect of pre-mobilization TENS in pediatric patients in the patients' postoperative period.

4. Conclusion

This method is important to control pain before mobilization in pediatric patients in the postoperative period. We believe that pre-mobilization TENS will positively affect pain and fear in patients aged 7-12 years undergoing abdominal surgery. This study will pave the way for further research on mobilization-related pain management in the postoperative period.

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Author Contributions

Küçükoğlu planned the study, KURT Sezer, Unuvar and Gunduz conducted data collection, and was responsible for the data collecting and writing the manuscript. Professor Küçükoğlu was responsible for the data analysis and evaluation of data and Kurt Sezer reviewing/proofing the manuscript.

Conflict of interest

The authors declare that they have noconflicting interests.

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References

[1] Chou R. Management of Postoperative Pain: A Clinical Practice Guideline From the American Pain Society, the American Society of Regional Anesthesia and Pain Medicine, and the American Society of Anesthesiologists' Committee on Regional Anesthesia, Executive Commi. *The Journal of Pain* (2016) **17**(2):131–157. doi:10.1016/j.jpain.2015.12.008.

[2] Purser L, Warfield K, Richardson C. Making Pain Visible: An Audit and Review of Documentation to Improve the Use of Pain Assessment by Implementing Pain as the Fifth Vital Sign. *Pain Management Nursing* (2014) **15**(1):137–142. doi:10.1016/j.pmn.2012.07.007.

[3] Villacres S, Chumpitazi CE. Acute Pediatric Pain Management in the Primary Care Office. *Pediatric Annals* (2018) **47**(3). doi:10.3928/19382359-20180222-01.

[4] Gai N, Naser B, Hanley J, Peliowski A, Hayes J, Aoyama K. A practical guide to acute pain management in children. *Journal of Anesthesia* (2020) **34**(3):421–433. doi:10.1007/s00540-020-02767-x.

[5] Gaglani A, Gross T. Pediatric Pain Management. *Emergency Medicine Clinics of North America* (2018) **36**(2):323–334. doi:10.1016/j.emc.2017.12.002.

[6] Makhlouf MM, Garibay ER, Jenkins BN, Kain ZN, Fortier MA. Postoperative pain: factors and tools to improve pain management in children. *Pain Management* (2019) **9**(4):389–397. doi:10.2217/pmt-2018-0079.

[7] Vance C, Dailey DL, Rakel BA, Sluka KA. Using TENS for pain control: the state of the evidence. *Pain Management* (2014) **4**(3):197–209. doi:10.2217/pmt.14.13.

[8] Moon S-H, Choi J-H, Park S-E. The effects of functional electrical stimulation on muscle tone and stiffness of stroke patients. *Journal of Physical Therapy Science* (2017) **29**(2):238–241. doi:10.1589/jpts.29.238.

[9] Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ (Clinical research ed.)* (2010) **340**:c869. doi:10.1136/bmj.c869.

[10] Fiorelli A. Control of post-thoracotomy pain by transcutaneous electrical nerve stimulation: effect on serum cytokine levels, visual analogue scale, pulmonary function and medication. *European Journal of Cardio-Thoracic Surgery* (2012) **41**(4):861–868. doi:10.1093/ejcts/ezr108.

[11] Ali S. Reported practice variation in pediatric pain management: a survey of Canadian pediatric emergency physicians. *CJEM* (2014) **16**(05):352–360. doi:10.2310/8000.2013.131261.
[12] Wong DL, Baker CM. Pain in children: comparison of assessment scales. *Pediatric nursing* (1988) **14**(1):9–17.
[13] Garra G. Validation of the Wong-Baker FACES Pain Rating Scale in Pediatric Emergency Department Patients. *Academic Emergency Medicine* (2010) **17**(1):50–54. doi:10.1111/j.1553-2712.2009.00620.x.
[14] Erdogan B, Ozdemir A. The Effect of Three Different Methods on Venipuncture Pain and Anxiety in Children: Distraction Cards, Virtual Reality, and Buzzy® (Randomized Controlled Trial. *Journal of Pediatric Nursing* (2021) **58**:54–62. doi:10.1016/j.pedn.2021.01.001.
[15] McKinley S, Coote K, Stein-Parbury J. Development and testing of a Faces Scale for the assessment of anxiety in critically ill patients. *Journal of Advanced Nursing* (2003) **41**(1):73–79. doi:10.1046/j.1365-2648.2003.02508.x.
[16] Gerceker G, Ayar D, Özdemir Z, Bektaş M. Çocuk Anksiyete Skalası-Durumluluk ve Çocuk Korku Ölçeğinin Türk Diline Kazandırılması [Introduction of the Child Anxiety Scale-State and Child Fear Scale into Turkish]. *Dokuz Eylül Üniversitesi Hemşirelik Fakültesi Elektronik Dergisi* (2018) **11**(1):9–13.
[17] Chan A-W. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ* (2013) **346**(jan08 15):7586. doi:10.1136/bmj.e7586.
[18] Lim Y, Godambe S. Prevention and management of procedural pain in the neonate: an update, American Academy of Pediatrics, 2016. *Archives of disease in childhood - Education & practice edition* (2017) **102**(5):254–256. doi:10.1136/archdischild-2016-311066.
[19] Tokuda M, Tabira K, Masuda T, Nishiwada T, Shomoto K. Effect of Transcutaneous Electrical Nerve Stimulation after Abdominal Surgery. *Rigakuryoho Kagaku* (2013) **28**(4):415–421. doi:10.1589/rika.28.415.
[20] Elboim-Gabyzon M, Najjar S, Shtarker H. Effects of transcutaneous electrical nerve stimulation (TENS) on acute postoperative pain intensity and mobility after hip fracture: A double-blinded, randomized trial. *Clinical Interventions in Aging* (2019) **14**(10):1841–1850. doi:10.2147/CIA.S203658.