

## ORIGINAL ARTICLE

Medicine Science 2024;13(4):815-21

## A new method of distracting attention: Is it effective for pain and fear during phlebotomy in children?

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Received 22 August 2024; Accepted 23 September 2024

Available online 15 October 2024 with doi: 10.5455/medscience.2024.06.061

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### Abstract

This study examined the impact of a novel distraction approach on the mitigation of fear and pain experienced by children between the ages of 7 and 12 during phlebotomy procedures. A total of 246 children who underwent phlebotomy between January and March 2019 in the pediatric blood collection unit were included in this randomized controlled trial. The participants (n=246) were randomized to the intervention (n=123) and control groups (n=123). A musical blood collection tube was used in the intervention group. The Personal Information form, the Children's Fear Scale (CFS), and the Faces Pain Scale-Revised (FPS-R) were used for the collection of the data. Fear and pain were primary and secondary outcomes, respectively. A formal approval from the ethics committee was sought in order to proceed with the study. In this study, the CONSORT checklist was used as a guide and ethical principles were followed. The pain intensity and fear level of the children in the intervention group (CFS=1.73±1.07; FPS-R=1.65±1.33) were lower than those in the control (CFS=2.86±1.07; FPS-R=3.09±1.57). The reduction in the intervention group's pain intensity and fear level differed significantly (p=0.000 and p=0.000, respectively). The results showed that using the musical blood collection tube as a new distraction technique reduces fear and pain intensity during phlebotomy in children. The musical blood collection tube can be used by health professionals as a non-pharmacological method to reduce the pain and fear of children during blood collection.

**Keywords:** Child, distraction, fear, pain, phlebotomy

### Introduction

Children might be subjected to painful procedures carried out because of diagnosis, follow-up or treatment in hospital settings [1]. Painful procedures create negative experiences for children. These can lead to negative emotional and psychological consequences [2]. Phlebotomy, vascular access, intramuscular injection and vaccination are some of the painful medical procedures that are frequently performed on children, causing anxiety, distress and fear [3]. The American Academy of Pediatrics states that all possible efforts should be made in order to reduce the pain that might be experienced by children due to painful medical interventions [4]. It is extremely important to use methods that have a pain-reducing effect during these procedures. Pharmacological and nonpharmacological methods might be applied together in order to reduce pain associated with

phlebotomy in children [5,6].

Non-pharmacological pain management includes cognitive-behavioural and physical approaches. Cognitive-behavioral techniques are effective in both engaging youngsters and diverting their attention away from distressing and agonizing treatments [7]. The most commonly used method with a high level of evidence is to distract the child's attention. Studies report them as being effective for individuals who are below the age of 12 years [8]. Many studies support non-pharmacological approaches' effectiveness in the management of pain associated with invasive procedures [7,9].

Non-pharmacological pain interventions are an integral part of the care given to children experiencing pain. In order to manage pediatric pain, these techniques can be applied either alone or

### CITATION

Aydemir Sahin M, Cigerci Y, Cevik Ozdemir HN. A new method of distracting attention: Is it effective for pain and fear during phlebotomy in children?. Med Science. 2024;13(4):815-21.



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in conjunction with pharmaceutical techniques, depending on the needs of the kid [7]. Accordingly, nurses ought to be skilled in managing uncomfortable operations in order to lessen their impacts and shield kids from the long-term ramifications of discomfort [10].

The distraction technique aims to increase pain tolerance and reduce the pain sensitivity of children by enabling them to focus on a stimulus other than pain [7]. Many "distraction" methods are used to reduce pain in procedures such as phlebotomy, vaccination, injection, and burn dressing in children. Watching cartoons, listening to music, kaleidoscope, distraction cards, blowing balloons, coughing, toys, books, cold and vibrating medical devices, and virtual reality are some of these techniques [11,12]. The choice of these methods differs according to children's age and developmental stages [13].

Research in the literature demonstrates how various distraction strategies can improve children's perceptions of pain across a range of age groups [13,14], as well as studies showing that it has no effect [15,16].

Despite the fact that numerous research have examined the impact of various diversion strategies on children's discomfort [5,17,18], the number of studies examining auditory or strategies for visual distraction impact on pain and fear is limited [13,19,20]. Applications grounded in empirical data are required to examine how various audio-visual distraction strategies affect children's pain and anxiety.

In this study, it was aimed to examine the effect of a new distraction intervention on pain and fear during phlebotomy in children between 7 to 12 years of age. Within the research, a new distraction tool (musical blood collection tube), which was designed as practical, useful, economical and child-friendly, was used to reduce the fear and pain perceived by children during phlebotomy. The musical blood collection tube is a completely new distraction tool designed by the 1st and 2nd authors to be used during phlebotomy when children experience pain and fear. It is an innovative approach that aims to distract children by activating their visual and auditory senses simultaneously, thereby reducing their feelings of pain and fear. Unlike traditional distraction methods that usually focus on a single sensory modality, this tool combines both visual and auditory stimuli in a unique way. Considering the scarcity of studies examining the effect of audiovisual distraction strategies in the existing literature, this study is thought to make an important contribution to the literature.

### *The hypotheses for the study were;*

**H1:** The audio-visual distraction technique (musical blood collection tube) is effective in reducing children's fear of the phlebotomy procedure.

**H2:** The audio-visual distraction technique (musical blood collection tube) reduces the pain levels children perceive during phlebotomy.

## Material and Methods

### Study Design

From January to March 2019, this intervention study was carried out in the pediatric phlebotomy department of a public hospital in Antalya.

### Participant Selection

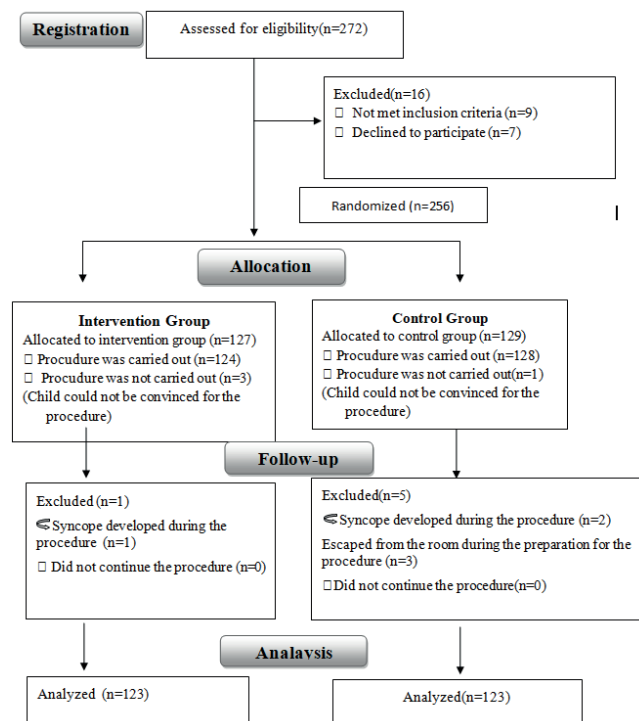
**Inclusion Criteria:** Kids between the ages of 7 and 12 who offered to take part, who had a phlebotomy procedure before, who did not have chronic pain, and who did not have any communication or mental problems, were included in the study.

**Exclusion Criteria:** Children with chronic illnesses, those who declined to take part in the trial, who had a fever and risk of neurological disease, who had taken analgesics in the last 12 hours, who had a history of hospitalization, who had an unsuccessful phlebotomy procedure at the first attempt, and who had syncope during the procedure were not included in this study.

### Setting

**Sampling:** The sample size was calculated with the Gpower 3.1.0 statistical program and a pilot study. Accordingly, considering the effect size was  $d=0.36$ , the alpha value was  $\alpha=0.05$  and the theoretical power was 0.80 (1-beta), the total sample size was calculated as 136, with a minimum sample size of 68 for each group. During the implementation phase, the study's power was increased by included all 246 children who met the inclusion criteria.

**Randomization:** Using the basic randomization procedure, 246 participants were split into two groups: intervention and control groups (Figure 1).



**Figure 1.** Randomized controlled trial flowchart

## Measures

Data collection was carried out with face-to-face interview technique by using personal information form (gender, age, previous phlebotomy experiences, etc.), the Children's Fear Scale (CFS) for fear, and the Faces Pain Scale-Revised (FPS-R) for pain. In addition to these tools, the musical blood tube designed and developed by the researchers was used as a distraction tool.

**Primary Outcome:** Researchers and healthcare providers can easily assess the pain experienced by children by using the CFS, which was developed by McMurty et al. (2011). It consists of five drawn facial expressions, ranging from neutral expression (0=no anxiety) to scared face (4=severe anxiety). The reliability and validity of the scale in Turkish was completed by Gerçeker et al (2018) [21]. Before, during and immediately after the phlebotomy, the participants were asked to tell which of the facial expressions on the scale reflected their level of fear. The researcher marked the facial expression that the children mentioned.

**Secondary Outcome: FPS-R:** FPS-R measures how children feel in their inner world instead of how their faces look. It is scored 0,2,4,6,8, or 10 according to the selected face. While 0 indicates the absence of pain, 10 indicates severe pain [22]. The FPS-R have been proven to be suitable for children from 3 years of age [23]. Pain assessments of children were performed during and immediately after phlebotomy.

## Intervention

The standard phlebotomy procedure was applied to all the participants. In standard phlebotomy practice, the child is taken to the chair where the procedure would be performed and the procedure is carried out straight away. No non-pharmacological methods were used to reduce the child's pain, fear and anxiety before, during or after the procedure. During the operation, parents belonging to both groups were permitted to remain with their children.

**Control group:** The personal information form was used to obtain the demographic and past experience data of the control group participants. Their fear levels were assessed before the phlebotomy procedure. The phlebotomy procedure was performed as per the standard protocol. Fear levels and pain severity of the children were assessed during the procedure. Immediately after the procedure, pain severity and fear levels were assessed once again.

**Intervention group:** The form for personal information was used to obtain the demographic and past experience data of the children in the intervention group. Their fear levels were assessed before the phlebotomy procedure. A musical blood collection tube designed by the researchers was used as the distraction tool during the phlebotomy procedure. First, the child sat on the chair in the blood collection unit. Then, the musical blood collection tube was placed at a point which was opposite the chair, where the child could easily see it during the procedure.

During phlebotomy, the distraction tool was turned on. Then, the child was asked to "read the writings on the musical blood collection tube out loud, count the number of times the blood filling image in the tool was repeated, and focus on the blood collection tube". It was ensured that the child was watching the distraction tool and phlebotomy was carried out. Children's fear levels and pain severity were assessed during the procedure. Immediately after the procedure, pain severity and fear levels were assessed once again.

## Distraction tool: Musical Blood Collection Tube

The distraction tool used in the study was designed by two researchers in 2016 and accepted by TUBITAK, a national institution, as a 2209A project. Under this project, the planning and design of the tool were carried out and a prototype was created. This tool which has been named the "musical blood collection tube" by researchers is a new distraction tool that would appeal to children's visual and auditory senses.

The musical blood collection tube tool, approximately 80 cm in length, has two arms, the right one is fixed and the movable on the left. There is a smiley face on the yellow cap on the top section of the tool. A red LED light is placed inside the interior of the body section, which is made of transparent polyethylene material. Red LED light is used to create the image of blood particles filling into the blood tube. Favourite children's songs were uploaded into the memory of the tool and it was made musical (Figure 2).



Figure 2. Musical blood collection tube

## Data Collection

Data were collected by one of the researchers through observation and face-to-face interviews with children between January and March 2019 in the pediatric blood collection unit between 14:00 and 16:00. Before the procedure for gathering data, the participants and their parents were given information about the study purpose and verbal and written informed consent was obtained from them. Two nurses carried out the phlebotomy procedure.

Data Analysis

The SPSS for Windows 24.0 was used for all statistical analysis. The information gathered from the personal information form and the scales were analyzed using descriptive statistical tests (number, percentage, mean, standard deviation, median, minimum and maximum). The Shapiro-Wilk and Kolmogorov-Smirnov Tests were used to test whether the data had normal distribution ( $p<0.05$ ). In the analysis of the data, when there was a normal distribution, the dependent sample t-test was used since there were two repetitions in the comparison of quantitative data in repeated measurements while an independent sample t-test was carried out for the comparison of the measurement of two independent groups in the intervention and control groups. In cases where the normal distribution was not achieved, the Wilcoxon sign test was used since there were two repetitions for the comparison of the quantitative data in repeated measurements while the Mann-Whitney U test was carried out for the comparison of the measurement of two independent groups in the intervention and control groups. The difference

between measurements at different times between dependent groups was analyzed with the Repeated Measures ANOVA. Two-Way Repeated Measures ANOVA was used to examine the effect of the independent variable on the related measures. Chi-square analysis, which is carried out for the analysis of the relationship between categorical variables, was used to confirm the homogeneity of the participants in the distraction and control groups.  $p < .05$  was taken as the statistical significance.

Ethical approval

The approval was obtained from the scientific research ethics committee of the concerned university (IRB: 2019/37) for the study. The children and their parents were informed about the goal and methodology of the study before giving their verbal and written agreement. The research was registered on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) with the ID number: NCT04513873.

Results

The distribution of the participants according to sociodemographic characteristics is presented in Table 1.

Table 1. Characteristics of children

| Characteristics                                          | Intervention group<br>(n=123) | Control group<br>(n=123) | Analysis  |
|----------------------------------------------------------|-------------------------------|--------------------------|-----------|
| Age (y) ( $\bar{x}\pm SD$ )                              | 9.39 $\pm$ 1.70               | 9.43 $\pm$ 1.73          | P=0.827*  |
|                                                          | n (%)                         |                          |           |
| Gender                                                   |                               |                          |           |
| Female                                                   | 63 (52.1)                     | 58 (47.9)                | P=0.524** |
| Male                                                     | 60 (48.0)                     | 65 (52.0)                |           |
| Education status                                         |                               |                          |           |
| Primary school                                           | 78 (48.4)                     | 83 (51.6)                | P=0.453** |
| Secondary school                                         | 45 (53.6)                     | 39 (46.4)                |           |
| Experience of having a phlebotomy procedure              |                               |                          |           |
| Yes                                                      | 118 (95.9)                    | 118 (95.9)               | P=0.487** |
| No                                                       | 5 (4.1)                       | 5 (4.1)                  |           |
| Reactions to phlebotomy procedure                        |                               |                          |           |
| Calm                                                     | 9 (7.3)                       | 10 (8.1)                 | P=0.642** |
| Timid                                                    | 43 (35.0)                     | 40 (32.5)                |           |
| Crying intensely                                         | 45 (36.6)                     | 38 (30.9)                |           |
| Shaking                                                  | 11 (8.9)                      | 10 (8.1)                 |           |
| Running away or not letting the procedure be carried out | 12 (9.8)                      | 19 (15.4)                |           |
| Aggressive behaviour                                     | 3 (2.4)                       | 6 (4.9)                  |           |

\*Mann Whitney U Test, SD: standard deviation

The distribution of fear according to groups is presented in Table 2. There was a significant difference between the groups in their fear levels. The fear levels of the distraction group during and after the procedure (Distraction group before the procedure: 1.73 $\pm$ 1.07, after the procedure: 0.60 $\pm$ 0.92) were significantly lower compared to the control group (Control group before the procedure: 2.86 $\pm$ 1.07, Control group after the procedure:

1.87 $\pm$ 1.27). While the fear level of the distraction group decreased during the procedure, the fear level of the control group increased significantly (Table 2).

The level of fear in the distraction group before the procedure (2.12 $\pm$ 1.09) decreased by 71.6% after the procedure (0.60 $\pm$ 0.92). The level of fear in the control group before the procedure (2.12 $\pm$ 1.09) decreased by 10.95% after the procedure (1.87 $\pm$ 1.27).

Table 2. Comparison of fear scores of groups

| Groups             | CFS                       |                           |                          | X <sup>2</sup> | p <sup>2</sup> | p <sup>3</sup> |       |        |
|--------------------|---------------------------|---------------------------|--------------------------|----------------|----------------|----------------|-------|--------|
|                    | Fear before the procedure | Fear during the procedure | Fear after the procedure |                |                |                |       |        |
|                    | $\bar{x}\pm SD$           | $\bar{x}\pm SD$           | $\bar{x}\pm SD$          |                |                |                |       |        |
| Intervention group | 2.12±1.09                 | 1.73±1.07                 | 0.60±0.92                | 149.438        | 0.000          | 0.000          | 18.1% | 71.69% |
| Control group      | 2.10±1.04                 | 2.86±1.07                 | 1.87±1.27                | 96.968         | 0.000          |                | 81.9% | 10.95% |
| U                  | 7425.000                  | 3600.500                  | 3252.000                 |                |                |                |       |        |
| p1                 | 0.795                     | 0.000                     | 0.000                    |                |                |                |       |        |

\*p<0.05; p<sup>1</sup>: Mann-Whitney U test, p<sup>2</sup>: repeated measures ANOVA, p<sup>3</sup>: two-way repeated measures ANOVA, CFS: Children's Fear Scale

The distribution of FPS-R pain scores according to groups is presented in Table 3. A statistically significant difference was found between the groups in the FPS-R pain scores. This study showed that the mean pain score on the FPS-R scale was lower in the intervention group (musical blood collection tube) than the pain score in the control group (p=0.000) (Table 3).

The mean pain score during the phlebotomy (1.65±1.33) of the distraction group participants decreased by 64% after the procedure (0.58±0.99). The pain perceived by the control group during the procedure (3.09±1.57) was higher compared to the pain after the procedure (1.74±1.59) and there was a 43% decrease in the pain level after the procedure. The mean pain score of the control group during the procedure was significantly (p=0.000) higher compared to the intervention group.

Table 3. Comparison of the pain scores according to groups

| Groups             | FPS-R                     |                          | p*    | p**   | Change during and after the procedure |
|--------------------|---------------------------|--------------------------|-------|-------|---------------------------------------|
|                    | Pain during the procedure | Pain after the procedure |       |       |                                       |
|                    | $\bar{x}\pm SD$           | $\bar{x}\pm SD$          |       |       |                                       |
| Intervention group | 1.65±1.33                 | 0.58±0.99                | 0.000 | 0.000 | 64%                                   |
| Control group      | 3.09±1.57                 | 1.74±1.59                | 0.000 |       | 43%                                   |

\*Wilcoxon test, \*\*Mann Whitney U Test; SD: standard deviation, FPS-R: Revised Face Pain Scale

Discussion

Phlebotomy, injection and vaccination procedures are some of the medical procedures that cause pain in children [24]. The American Society for Pain Management Nursing states that optimal pain control should be provided before and during painful procedures [25]. In recent years, techniques for non-pharmacological distraction have been widely employed to control pain during basic medical procedures like phlebotomy [8,21].

Research indicates that music therapy is a useful tool for mitigating children's pain and anxiety during painful procedures such as phlebotomy [13,26]. In this study, the group receiving the musical blood collection tube instrument as a phlebotomy intervention experienced less discomfort than the control group. Studies that used music intervention during medical procedures reported that the intervention reduced pain, anxiety and aggressive behaviours of the participants [18,27-29]. Similar to the results of previous studies, in this study, the pain score of the distraction group during the phlebotomy procedure decreased by 64% after the procedure. This finding supports our hypothesis H2. Based on these results, it can be thought that musical distraction techniques activate the visual and auditory senses of children and step up their focus.

Kristjansdottir and Kristjansdottir (2011) found that the groups receiving vaccinations while listening to various musical recitals experienced less discomfort than the control group in their randomized controlled research on adolescents [28]. According to a different study, children aged 3 to 11 who are undergoing intravenous cannulation benefit from music therapy, which effectively lowers their levels of fear and pain [30]. Similarly, Caprilli et al. (2007) revealed that the use of interactive music as a distraction method during ven puncture in children reduces pain and stress [31]. In our study, the participants in the intervention group had lower anxiety levels during and after the phlebotomy procedure compared to the control group, which was statistically significant. This finding supports our hypothesis H1. In this respect, our results show similarities to the literature. In contrast to the findings of these investigations, there exist more research wherein the effect of music during medical procedures could not be determined clearly [15,32]. Children's age, gender, severity of pain, type of medical procedures, and variety of distraction techniques might be the reasons for the differences in study results.

Considering the age differences and periodical characteristics of children during invasive painful procedures, various distraction techniques such as kaleidoscope, audiovisual distraction and coughing and blowing balloons were used in studies [8,13].

When children had phlebotomies, the musical blood collection tube with audiovisual features helped to lessen their discomfort and anxiety. This supports the previous literature findings that audiovisual distraction techniques were used.

## Conclusion

The study findings show that the musical blood collection tube tool used during phlebotomy has a pain and fear-reducing effect on children in the 7-12 age group. The musical blood collection tube offers a practical, cost-effective and child-friendly solution that can be integrated into routine clinical practice during phlebotomy to reduce the distress and improve the overall experience of paediatric patients. Nurses and other healthcare professionals should be able to effectively manage the fear pain and pain that occur during medical procedures performed on children. In this direction, the musical distraction tool can be used routinely in children during phlebotomy. The results of the study will contribute to studies investigating effective pain and fear-reducing techniques and distractors for various painful procedures. It may be recommended to evaluate and test the effect of this new tool as a distraction technique on children of different age groups and painful procedures.

## Limitations

There are several restrictions on this study. First, this study did not have double-blinding. Therefore, the researchers were aware of whether the participant was in the intervention or control group. Second, the children's self-reports were used in the assessment of pain and fear. To avoid any possible bias, both nurses and parents could be asked to evaluate the children's fear and pain.

## Conflict of Interests

*The authors declare that there is no conflict of interest in the study.*

## Financial Disclosure

*The distraction tool used in the research was financed by TUBİTAK as project 2209A.*

## Ethical Approval

*The Afyonkarahisar Health Sciences University Research Ethics Committee approved the research. Ethics committee approval dated 2019 and numbered 37 was obtained.*

## Acknowledgments

*We would like to sincerely thank the participants who volunteered in this study.*

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