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Trial protocol for an experimental study comparing Tracing Image and Coloring for Kids with two passive distractions during peripheral intravenous cannulation on pain and fear in children

Introduction

Peripheral intravenous cannulation (PIVC) is an invasive technique. In this technique, a catheter is entrenched through the skin of the recipient into the lumen of a peripheral blood-vein. It is the second most painful procedure performed in hospitals [1]. Peripheral intravenous cannulation (PICV) is a common painful procedure for children, and nearly all ill children have experience with PIVC [2], and up 80% of patients receive a peripheral venous cannula in a hospital [3]. Therefore, use of effective methods in pain and anxiety relief is very important during injection procedures in children.

A blood injection-injury phobia occurs at the severe level of needles fear which is a disorder in the Diagnostic and Statistical Manual of Mental Disorders (5th edition) [4]. Anxiety of needles is significant since most inpatient children have an IV that is required with several illnesses to administer medicines, fluids, and prescriptions[2]. Poor management of children›s pain is associated with long-term physical and psychological health issues, including needle phobia, avoidance of medical care, and intolerance to [5].

In order to relieve pain and anxiety in children undergoing PICV. Psychological and physical approaches for coping with children›s pain are favored, as well as pharmacological methods [6]. Application of topical anesthetic creams is the most commonly used pharmacological solution to reduce pain associated with the medical procedure [7], or refrigerant preparations, however, only reduce the perception of pain in children during procedures [8]. These approaches are not resolve anxiety, a core factor of noncooperation, which encumbers the efficiency of the needle procedure. For this cause, non-pharmacological approaches are generally recognized as alternative techniques, which may be used separately or in addition to pharmacological approaches, to provide sufficient pain and anxiety relief and to offer children a sense of control over the situation [9].

Distraction is a non-pharmacological technique that moves focus away from anxiety, discomfort or unpleasant stimulation to more stimulating or friendly stimulation. Distraction is one of the most effective, simplest and inexpensive non-pharmacological pain management methods [10]. The benefits of using non-pharmacological methods include decreased pain, distress, and anxiety reported by the parent, child, and/or observer [11]. There are two main types of distraction techniques: active and passive [12, 13].

Objectives:

To evaluate the roles of the TICK-B, listening music, and watching cartoon, in relieving pain and fear of school-age children during PIVC.

To compare the effect of TICK-B with the effects of the listening music, and watching cartoon, on reducing pain and anxiety during PIVC in children.

To compare the effects of three distraction groups with the control group in relieving pain and anxiety during PIVC.

Hypothesis:

H1: There will be a significant difference between the pain and anxiety scores of children in the experimental and control group.
H2: There will be no significant difference between the pain and anxiety scores of children in the experimental and control group.

Statement of the Problem:

"Pain and Anxiety are the sources of PIVC procedure, this study to evaluate the efficacy of distractions on pain anxiety among children (6-12) at HPTH undergoing PIVC through comparison between all distractions groups & with the control group».

Patients and Methods

In this study, a four-arm, randomized, superiority trial will be conducted. SPIRIT-PRO (Standard Protocol Items: Recommendations for Interventional Trials) reporting guidelines are used for the study protocol.

Study design:

We will run a randomized controlled trial to test the effectiveness of three distractions (TICK-B, listening to music, and watching cartoons) at Heevi Pediatric Teaching Hospital (HPTH), Duhok city / Kurdistan region for children 6-12 years undergoing PIVC procedure.

Setting and samples:

The setting is the physical condition and location in which data collection takes place in the study (Polit & Beck, 2009). Selection of the area for the study is one of the essential steps in the research process. The selection of settings for the present study was on the basis of availability of the subjects, feasibility of conducting the study, the economy of time, and energy. The study will be conducted in wards / HPTH. Hospitals in Iraq and Kurdistan regions generally do not use pharmacological and non-pharmacological approaches to reduce pain and anxiety during venipuncture procedures.

Variables under the study (Population/ Sample, Sample size)

Target Population:

Target population is the aggregate of all the cases with a certain phenomenon about which the researcher would like to make generalization (Polit & Beck, 2009).
Target populations for this study are the nurses working in pediatric wards & children who are undergoing PIVC procedures in HPTH.

Sample Size

To calculate the sample size, the observer assessed the pain levels of the first five cases in the control group. We measured the mean value and standard deviation of these five cases accordingly. The obtained score was 6.53 (Sta. deviation: 1.5). We believed the intervention would have a large effect on pain in this study. Therefore, we assumed that this value could decrease to 5.53 (SD: 0.85) after the intervention. The effect size d was 0.820; two tails, α; 0.05 and power (1-β); 0.95 was considered using the two independent groups. The required number of patients in each group was 30. We plan to recruit 80 patients with usable data, which will allow sufficient power to find a difference in both primary outcomes if a difference truly exists and account for missing data.

Eligibility criteria

Inclusion:

School aged 6-12 years old.
Children who require PIVC.

Exclusion:

1. Chronic diseases,
2. Physical impairment,
3. Disability contributing to difficult communication,
4. Children of unsatisfied parents,
5. Children with neurodevelopment delay,
6. Cognitive impairment, hearing impairment or visual impairment,
7. Taking an analgesic within 6 hours, or those with a syncope history.

Time framework for Study:

March 2022 to Jun 2022.

Measurement/instruments:

Demographic characteristics: The demographic characteristics of the patients will be recorded in a designed questionnaire called as Child Family Form. They characteristics were children's age, gender, and hospitalization, number of prick, parental age, and educational status.

TICK-B group: The children will receive the pictures they want. They will be asked to trace and color the pictures that need coloring. The nurse will color with children during the procedure. And after the procedure, the child will take his or her picture which he colored during the procedure.

Watching cartoons: In this group, children will watch cartoons as they like. Watching will continue until the procedure is complete.

Listening to music: In this group, children will listen to cartoon music as they like. Listen will continue until the procedure is complete.

Control group. The kids in this group will be allowed to keep their family near. The routine blood taking procedure was applied.

Outcomes

The level of **pain** resulting from the applied procedure in each child will be assessed by the self-reports using the Wong-Baker FACES (WB-FACES) pain rating scale. The WB-FACES scale is a 0 to 10 scale, showing six cartoon faces that range from a neutral expression (0=very happy/ no hurt) to a crying face (10=hurts as much as you can imagine).

Children Fear Scale (CFS) will be used to evaluate the children's level of **anxiety**. CFS is a 0 to 4scale, showing five cartoon faces that range from a neutral expression

(0=no anxiety) to a frightened face (4=severe anxiety). Pre-procedural and procedural pain, as well as anxiety, for all children was evaluated using CFS by both parents and the researcher.

Fear and Pain: Visual Analog Scale (**VAS**) will be used to measure pain and fear of children by **parent** and **observer**. The rating of 0 represents no pain and 10 represents the worst or most severe pain. After the procedure, observer and parents will report their assessment of how much fear and pain the child experienced after the blood test using VAS with the endpoints "No fear" to "Most fear", and "No pain" to "Worst pain".

Ethics and dissemination

Participation in the study carries no known risks for the children, will cause no significant inconvenience to the family, and will not cause any additional suffering to the children. Children will receive the same standard care as other patients during the cannulation procedure. All protocol amendments will be submitted for approval to the general director of health in Duhok and the manager of the Heevi Pediatric Teaching Hospital prior to implementation and incorporated into the ClinicalTrials.gov trial registration. TICK-B›s cost is lower than other distraction techniques, so it can be used in low-resource settings. The results of this study will be published in a high-impact, peer-reviewed journal and presented at national and international meetings. Authorship eligibility will be determined by following the recommendations of the International Committee of Medical Journal Editors [14]. For this trial, a technical online appendix, statistics code, and dataset are available upon request.

Results:

The findings are to be analysed statistically by t-test for the means and chi-square for categoric differences. Factor analysis, ANOVA, ANCOVA, and regression analysis will be applied when needed.

Discussions:

The results will be discussed in relation to cultural context, age/gender differences, and the effectiveness of distractions on different clinical pediatric populations in relation to painful nursing procedures, all groups will be compared control group.

Patient consent for publication: will Not require.

Contributors: **SKS, FD and CA**, will develop and revise the protocol, co-drafted the protocol paper, and will operationalize the study**. FD and CA** led the statistical analysis planning and contributed to protocol revision. **SKS** is a pediatric researcher who will brings expertise in the study of non-pharmacological interventions in children. **SKS** is a researcher with expertise in psychology and distraction.

Funding: This study will be self-funding

Ethics approval: Will be by Director of Health in Duhok and Heevi Pediatric Teaching Hospital

Provenance and peer review: Will Not commissioned; externally peer reviewed.

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