Cover Page

Study Title:
The Effect of Drama-Based Coloring Storybooks on Children's Fear, Anxiety, and Pain Management in the Perioperative Process: "Alican's Brave Journey"

ClinicalTrials.gov Identifier (NCT Number):
NCT0XXXXXXX

Document Type:
Study Protocol + Statistical Analysis Plan+ Informed Consent Form

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1. STUDY PROTOCOL

1.1. Type of Study

This study is a **randomized controlled experimental study**. The study has been registered in the **ClinicalTrials.gov** database under registration number **…….** Reporting of the study will be conducted in accordance with the **Consolidated Standards of Reporting Trials (CONSORT)** (Hopewell et al., 2025) and the **TIDieR checklist** (Yakut et al., 2020).

1.2. Study Setting and Period

The study will be conducted between **January 2025 and June 2026** in the **Pediatric Surgery Department of Bingöl State Hospital**. The department consists of nine double-occupancy patient rooms. A total of six nurses and two pediatric surgeons are employed in the department. Nurses work in two shifts: 08:00–16:00 and 16:00–08:00, with two nurses on duty during the day shift and one nurse during the night shift. Children hospitalized in the department receive routine treatment, monitoring, and basic nursing care. Except for emergency surgeries, elective surgeries are performed two days a week.

1.3. Population and Sample

The study population will consist of children admitted to the **Pediatric Surgery Department of Bingöl State Hospital** for **inguinal hernia surgery**. The sample of the study will include children aged **6–9 years** who are scheduled for **circumcision**, have not undergone previous surgery, and have no visual, hearing, or speech impairments.

Prior to the study, a power analysis was performed using the **G*Power** software to determine the appropriate sample size. The purpose of this calculation was to determine an adequate sample size for the study, and **Cohen's standard effect sizes** were used as the reference method (Cohen, 1992). Based on an alpha error of **5% (α)**, a power of **90% (1−β)**, and a **one-tailed t-test**, the sample size was determined as **36 participants per group**, resulting in a total of **72 children**, with an effect size calculated as **0.69**.

1.4. Inclusion Criteria

Children who meet the following criteria will be included in the study:

- Aged between 6 and 9 years
- Scheduled for circumcision surgery
- Have not undergone previous surgery
- Have no visual, hearing, or speech impairments

1.4.1. Exclusion Criteria

Children who meet any of the following criteria will be excluded:

- History of previous surgery
- Presence of visual, hearing, or speech impairments

1.5. Randomization and Blinding

A total of 72 children who meet the inclusion criteria will be enrolled in the study; 36 will be assigned to the experimental group and 36 to the control group. Randomization will be carried out using **Random Allocation Software (Version 1.0.0)**. Subsequently, children will be stratified by age, and those aged 6–9 years will be distributed evenly between the experimental and control groups.

To objectively evaluate the effect of the intervention, participants will not be informed of their group assignments. Although the researcher implementing the intervention will be aware of the group allocations, no guidance or influence based on this information will be provided during the assessment process. This approach aims to minimize expectation effects related to the intervention and researcher bias.

1.6. Pilot Study

Prior to the main study, a pilot application will be conducted with **five children scheduled for surgery** to assess the feasibility and effectiveness of the intervention. During the pilot study, the applicability of the drama-based coloring storybook *"Alican's Brave Journey"*, children's comprehension levels, the age appropriateness of the activities, and the usability of the data collection tools will be evaluated. Based on the feedback obtained, necessary revisions will be made, and preparations for the main study will be completed. The results of the pilot study will be used to enhance the methodological rigor of the research.

1.7. Data Collection Instruments

Research data will be collected using the **Descriptive Information Form**, the **Children's Fear Scale (CFS)**, the **Modified Yale Preoperative Anxiety Scale (mYPAS)**, and the **Wong-Baker Faces Pain Rating Scale**. The intervention tool will be the drama-based coloring storybook *"Alican's Brave Journey"*, which will be developed using expert opinions.

1.7.1. Descriptive Information Form

The form consists of items related to the child's sex, age, height, weight, place of residence, number of siblings, previous hospitalization history, previous surgical history, mother's age and educational level, father's age and educational level, family economic status, and the type of surgery the child will undergo. The form was developed by the researchers (Appendix 1).

1.7.2. Children's Fear Scale (CFS)

The Children's Fear Scale was developed by McMurtry et al. (2011) to assess fear in children undergoing painful medical procedures. The validity and reliability of the Turkish version were established by Gerçeker et al. (2018). The scale consists of five faces ranging from a neutral expression (0 = no fear) to a highly fearful face (4 = severe fear). Children are asked to select the face that best represents their feelings. Higher scores indicate higher levels of fear (Appendix 2).

2.7.3. Modified Yale Preoperative Anxiety Scale (mYPAS)

This instrument measures preoperative anxiety in children aged two years and older. The Yale Preoperative Anxiety Scale (YPAS), developed in 1995 to assess preoperative anxiety in children, was modified in 1997 (mYPAS) and has been widely used in fields such as dentistry, anesthesia, surgery, and pediatrics. The validity and reliability of the Turkish version were established by Hatipoğlu et al. (2019).

The scale consists of 22 items and evaluates five domains: activity, vocalization, emotional expressivity, state of arousal, and interaction with family members. Activity, emotional expressivity, state of arousal, and interaction with family are rated on a scale from 1 to 4, while vocalization is rated from 1 to 6. The score for each category is divided by the maximum possible score for that category. All category scores are summed, divided by the total number of categories, and multiplied by 100, yielding a final score ranging from 23.33 to 100. Scores above 30 are classified as indicating anxiety, with higher scores reflecting higher anxiety levels (Appendix 3).

1.7.4. Wong-Baker Faces Pain Rating Scale

The Wong-Baker Faces Pain Rating Scale is an adaptation of the Faces Rating Scale, a projective technique that uses six facial expressions to assess pain in children (Wong, 1988). It is used to describe current pain intensity. Children are asked to select the face that best represents their pain. Face 0 represents a happy face indicating no pain, while face 5 represents a crying face indicating "the worst pain imaginable," although not necessarily requiring crying. Responses range from 0 (no pain) to 5 (worst imaginable pain) (Appendix 4).

1.7.5. Intervention Tool (Alican's Brave Journey Coloring Storybook)

The coloring storybook *"Alican's Brave Journey"* will be developed using a drama-based approach by a multidisciplinary team. The team will include a child psychologist, pedagogue, drama educator, pediatric nurse specialized in preoperative preparation, art therapist, child development specialist, pediatric surgeon, illustrator, and children's literature author.

These experts will develop age-appropriate scenarios and activities for children aged 6–9 years undergoing surgery. The child psychologist and pedagogue will ensure that the scenarios are structured to reduce children's fear and anxiety. The drama educator will develop creative drama techniques through the character Alican to facilitate empathy. The pediatric surgeon and the pediatric nurse specialized in preoperative preparation will provide accurate information about the surgical process, while the child development specialist will ensure developmental appropriateness. The art therapist and play therapist will offer artistic and play-based activities to support children's emotional expression. The illustrator will visually enrich the story, and the children's literature author will ensure the narrative is clear and engaging.

The scenarios will include stages such as hospital admission, wearing surgical clothing, transfer to the operating room, anesthesia, and Alican's recovery and discharge. These scenarios will be tested through pilot applications and revised based on feedback.

The book will be written in language and tone appropriate for children aged 6–9 years and will consist of a total of 10 pages. Each page will include one colored illustration and one uncolored (line-drawn) illustration, along with a short story aligned with the images. Children

will be provided with colored pencils and encouraged to color the uncolored illustrations freely.

1.8. Procedure

1.8.1. Experimental Group

When children are admitted to the clinic one day before surgery, routine information and procedures will be provided by clinical nurses. Before the implementation of the coloring storybook, the Descriptive Information Form, Children's Fear Scale (CFS), Modified Yale Preoperative Anxiety Scale (mYPAS), and Wong-Baker Faces Pain Rating Scale will be administered.

Subsequently, starting one hour before surgery, the storybook *"Alican's Brave Journey"* will be read to and/or by the child. The intervention will be implemented by a researcher certified in storytelling and creative drama. Since the book includes both colored and uncolored illustrations, children will be provided with coloring pencils and asked to color the uncolored images as they wish.

Fear, anxiety, and pain levels will be reassessed using the CFS, mYPAS, and Wong-Baker Faces Pain Rating Scale **10 minutes before surgery** and **60 minutes after surgery**. Completing the forms will take approximately 5–10 minutes.

If children experience fear due to the storybook content, emotional support will be provided, and it will be explained that such feelings are normal. Open communication will be established to identify distressing elements. Relaxation techniques, play therapy practices, and parental support will be used to facilitate emotional expression. In addition, providing accurate information about the surgical process will help reduce fear related to uncertainty. Finally, children will be encouraged to create their own stories to enhance self-confidence and coping skills.

1.8.2. Control Group

When children are admitted to the clinic one day before surgery, routine information and procedures will be provided by clinical nurses. The questionnaires and scales will be administered by the researcher one hour before surgery and repeated **10 minutes before surgery** and **60 minutes after surgery**. Completing the forms will take approximately 5–10 minutes.

1.9. Ethical Considerations

Prior to the study, the necessary institutional permissions were obtained from the **Bingöl Provincial Directorate of Health**. Ethical approval was obtained from the **Bingöl University Rectorate Scientific Research and Publication Ethics Committee of Health Sciences** with decision number **E-33117789-044-163219**, dated **26.06.2024**. Subsequently, **a new ethics committee approval was obtained due to a change in the study title**. Participation in the

study will be voluntary. Throughout the study, the principles of the **Declaration of Helsinki** will be strictly adhered to in order to protect individual rights.

2. STATİSTİCAL ANALYSİS PLAN

The data obtained in the study will be analyzed using the **SPSS** software. Descriptive statistics will be presented as numbers, percentages, means, and standard deviations. The normality of data distribution will be assessed using the **Kolmogorov–Smirnov test**. Independent samples t-test or Mann–Whitney U test will be used for between-group comparisons, while paired samples t-test or Wilcoxon test will be used for within-group comparisons. A p-value of **< 0.05** will be considered statistically significant.

3. INFORMED CONSENT FORM

Dear Parents,

We invite you to participate in the study titled ***"The Effect of a Drama-Based Coloring Storybook on Anxiety, Fear, and Pain Management in Children During the Perioperative Period: 'Alican's Brave Journey'."*** *Before deciding whether to participate in this study, it is important that you understand why and how the research will be conducted. Therefore, reading and understanding this form is essential. If there is anything you do not understand or find unclear, please ask the researchers.*

Participation in this study is entirely voluntary. You have the right not to participate or to withdraw from the study at any time, even after agreeing to participate. Completing this form will be considered as your consent to participate in the research.

Please answer the questions on the forms without any pressure or influence from anyone. The information obtained from these forms will be used solely for research purposes.

1. Information About the Study

a. Purpose of the Study:
This study is planned to determine the effects of the drama-based coloring storybook "Alican's Brave Journey" (formerly "Surgebuddy'nin Cesur Yolculuğu") on preoperative and postoperative anxiety, fear levels, and postoperative pain symptoms in children.

b. Reason for the Study:
This study is part of a doctoral thesis.

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2. Participation in the Study

I have read the information provided above and have fully understood the scope and purpose of the study I am asked to participate in, as well as my responsibilities as a volunteer. The study has been explained to me both verbally and in writing by the researcher named below. I have had the opportunity to ask questions and discuss the study, and I have received satisfactory answers. I have also been verbally informed about the possible risks and benefits of the study.

I understand that I can withdraw from this study at any time without giving a reason, and that withdrawing will not cause any negative consequences. Under these conditions, I voluntarily agree to participate in this research without any pressure or coercion.

Participant (written by themselves)

Name-Surname: _____
Signature: _____

For Minors or Those Under Guardianship

Parent/Guardian (written by themselves)
Name-Surname: _____
Signature: _____

Witness (if required)

Name-Surname: _____
Signature: _____

Researchers

Name-Surname: _____
Signature: _____

Note: This form is prepared in two copies. One copy is given to the volunteer against signature, and the other is kept by the researcher.

APPENDİX 1: Participant Information Form

1. **Age:** _____
2. **Height (cm):** _____
3. **Weight (kg):** _____
4. **Place of residence:**
    - Province: _____
    - District: _____
    - Village: _____
5. **Number of siblings (excluding the child):** _____
6. **Have you been hospitalized before?** Yes ( ) No ( )
7. **Have you undergone surgery before?** Yes ( ) No ( )
8. **Mother's age:** _____
9. **Mother's education level:**
    - Illiterate ( )
    - Primary school ( )
    - Middle school ( )
    - High school ( )
    - Associate degree ( )
    - Bachelor's degree ( )
    - Postgraduate degree ( )
10. **Father's age:** _____
11. **Father's education level:**

- Illiterate ( )
- Primary school ( )
- High school ( )
- Associate degree ( )
- Bachelor's degree ( )
- Postgraduate degree ( )

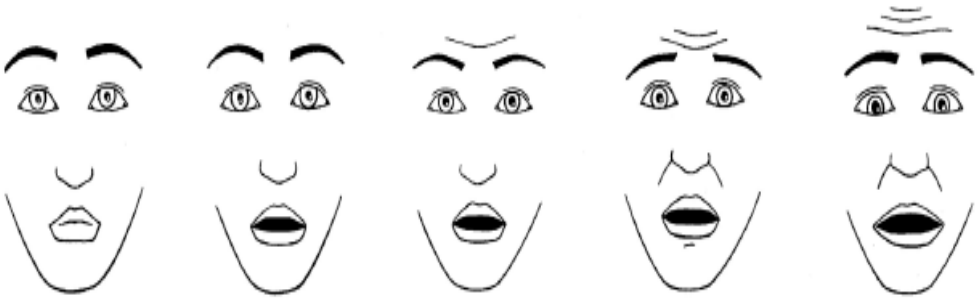
12. **Family economic status:**

- Income less than expenses ( )
- Income equal to expenses ( )
- Income greater than expenses ( )

Appendix-2. Children's Fear Scale (CFS)

Instructions: Please select the facial expression that best represents how you feel, on a scale from **0 to 4**.

- **0** = No worry
- **1** = Slight worry
- **2** = Moderate worry
- **3** = Strong worry
- **4** = Extreme worry



Appendix-3. Modified Yale Preoperative Anxiety Scale (mYPAS)

Activity

1. Looks around, plays with toys, active.
2. Does not play with toys, looks at the floor, fidgets with fingers, sucks thumb, sits close to family.
3. Pushes the mask away, moves wildly without focusing on anything, stays close to family.
4. Actively and aimlessly tries to leave the room, pushes everything with hands, arms, and whole body.

Vocalization / Sound

1. Reads, asks questions, comments, laughs.
2. Speaks in whispers and nods, appears adult-like.
3. Gives adult-like responses or is silent.
4. Groans quietly, whines, murmurs.
5. Cries.
6. Screams loudly.

Emotional Expression

1. Focused on toy, clearly happy, smiles.
2. Facial expression unreadable, neutral.
3. Looks sad, scared, with teary eyes.
4. Stressed, crying, very upset.

State of Arousal

1. Alert, looks around, watches the anesthetist.
2. Sits quietly, sucks thumb.
3. Alert, body tense, startles easily.
4. Groans in panic, tries to escape.

Use of Parents

1. Does not need parents, engages with toys.
2. Seeks parents, talks quietly with others.
3. Quietly asks for parents, watches obvious events.
4. Pushes parents away, keeps distance from parents.

Appendix-4. Wong-Baker Faces Pain Rating Scale