

STUDY PROTOCOL & INFORMED CONSENT FORM

*The Effect of Cartoons and Mobile Games on Reducing Preoperative Anxiety
and Fear in Children Admitted to the Surgical Ward with a Diagnosis of
Appendicitis: A Randomized Controlled Trial*

NCT Number: Not Yet Assigned - Pending

Document Date: Oct 22, 2025

SECTION 1: STUDY PROTOCOL & DATA COLLECTION FORMS

1.1 Sociodemographic Data Form

Research Code No:

Age:

Gender: () Female () Male

Previous Hospitalization History?:

Previous Surgical History:

Presence of Chronic Disease?: () Yes () No

Mother's Age:

Mother's Education Level: () Illiterate () Primary Education () High School () University

Mother's Occupation:

Father's Age:

Father's Education Level: () Illiterate () Primary Education () High School () University () Other:

Father's Occupation:

1.2 Physiological Measurement Form

PARAMETERS	PRE-PROCEDURE	POST-INTERVENTION
Pulse Rate (Heart Rate)		
SpO2 (Oxygen Saturation)		
Blood Pressure		

Fear Scale Score:

Modified Yale Preoperative Anxiety Scale (m-YPAS) Score:

SECTION 2: INFORMED CONSENT FORM (PARENTAL CONSENT)

PLEASE TAKE TIME TO READ THIS DOCUMENT CAREFULLY.

Study Title

The Effect of Cartoons and Mobile Games on Reducing Preoperative Anxiety and Fear in Children Admitted to the Surgical Ward with a Diagnosis of Appendicitis: A Randomized Controlled Trial

Purpose of the Research

The main purpose of this study is to investigate whether cartoon viewing and mobile gaming help reduce preoperative anxiety and fear in children aged 7–12 years. The results obtained will guide healthcare professionals in helping future pediatric patients experience a more comfortable preoperative period.

Risks and Discomforts

The cartoon-watching or mobile game-playing interventions applied in this study do not pose any physical risk or danger to your child's health. These are recreational activities performed in daily life. The greatest potential inconvenience arising from the study may be the short period of time you or your child will spend while providing information.

Benefits of the Study

The primary goal of this research is to contribute to the field of healthcare and future patients. These activities may help your child experience a more comfortable and peaceful preoperative process; however, there is no direct health or medical treatment benefit specific to the study itself.

Expected Responsibilities from Participants

If your child participates in the study, you and your child are expected to:

- Comply with the participation process of the activities (cartoon or mobile game) directed by the research team.
- Share accurate information regarding your child's condition and experiences with the nurse/research team throughout the study process.

Voluntary Participation and Withdrawal

Your child's participation in this study is completely voluntary. You may decline to participate, or you may withdraw from the study at any time after joining without providing any justification. You will not face any penalty, sanction, or loss of rights due to withdrawal. Your child's medical treatment and the healthcare services they receive will never be affected.

Confidentiality of Data

All records and information that could reveal your child's identity will be kept strictly confidential. Even if the results of the study are published in a journal or presented at a scientific meeting, your child's identity will never be disclosed and cannot be shared with the public.

For the purpose of verifying that the study is conducted in accordance with regulations, the Ethics Committee, authorized institutions, monitors, or auditors may review your child's original medical records related to the study. The confidentiality of this information will still be protected. By signing this form, you (the volunteer or legal representative) grant permission to these individuals to access these records solely to review the sections related to the research.

Institutional / Investigator Contact Information

- Affiliation: T.C. Ministry of Health, Provincial Health Directorate, Ankara Bilkent City Hospital
- Principal Investigator: Eda Emine YETKIN (Master's Student – Pediatric Nursing, Ankara Yıldırım Beyazıt Üniversitesi)
- Phone: 0530 137 58 79 (Available 24/7)

Termination of Participation

Your child's participation may be terminated under the following conditions:

- If you (parent/legal representative) or your child wish to withdraw from the study.
- If your child's health status prevents participation or if continuation is deemed inappropriate.
- If the investigator (Eda Emine YETKIN) deems it necessary for the continuation of the study.

Additional Information

- No blood samples, tissue, or any other biological materials will be taken from your child within the scope of this study.
- No fees will be requested from you or your social security institution for participation. All research expenses will be covered by the research budget.
- Your child will be informed about this study in a manner appropriate to their age and level of understanding, and their assent (consent) will be obtained. A separate "Child Information and Assent Form" has been prepared for children aged 9–12, and written assent will be obtained from your child.

Statement of Consent

I have read all the explanations in the informed consent form. Written and verbal explanations regarding the research, whose subject and purpose are stated above, were provided to me by the investigator named below. I am aware that my child will be informed in an age-appropriate manner and their assent will be obtained. I know that I participate in the study voluntarily and that I can withdraw my child from the study at any time with or without justification. I freely consent to my child's participation in this research without any pressure or coercion.

Volunteer (Mother/Father or Legal Representative):

Name-Surname:

Signature:

Date: / /

Investigator Providing Information:

Name-Surname:

Signature:

Date: / /

SECTION 3: CHILD INFORMATION AND ASSENT FORM

Study Title: The Effect of Cartoons and Mobile Games on Reducing Preoperative Anxiety and Fear in Children Admitted to the Surgical Ward with a Diagnosis of Appendicitis: A Randomized Controlled Trial

Investigator: Eda Emine YETKIN (Master's Student – Pediatric Nursing, Ankara Yıldırım Beyazıt University)

Hello!

I am Nurse Eda. I am inviting you to a study designed to help you feel more comfortable and reduce your fear before surgery. In this study, you will either watch cartoons or play mobile games before your surgery. These activities are designed to relax you and make you feel better in the hospital.

What You Need to Know

- This study will not hurt. No needles, medications, or painful procedures will be involved. You will only watch cartoons or play games.
- You can say "I don't want to do this anymore" whenever you want. If you choose not to participate, no one will be angry with you, and your medical treatment will continue exactly the same way.
- None of your information will be shared with others.

Why Would You Want to Participate?

If you participate in this study, you may feel more comfortable and happy before surgery. Furthermore, your participation can help other children feel better when they are in the hospital in the future.

Your Information Will Be Kept Secret

Your name and personal details will not be shared with anyone. Your name will not appear in any written reports.

If You Have Questions

You can ask me or the nurses looking after you questions at any time. Do not hesitate to ask — we are here to listen to you.

Your Decision

You can fill out the section below of your own free will:

I want to participate in this study.

[] Yes, I want to.

[] No, I do not want to.

I understand what is written above. I agree to participate in this study of my own free will. I know that I can stop whenever I want.

Child's Name-Surname:

Signature:

Date: / /

Investigator Providing Information:

Signature:

Date: / /

Parent / Legal Representative:

Signature:

Date: / /

STATISTICAL ANALYSIS PLAN (SAP)

Official Title: The Effect of Cartoons and Mobile Games on Reducing Preoperative Anxiety and Fear in Children Admitted to the Surgical Ward with a Diagnosis of Appendicitis: A Randomized Controlled Trial

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1. Sample Size Determination (Power Analysis)

The sample size for this study was determined using G*Power software (Version 3.1.9.7). The primary outcomes of the study are the preoperative anxiety scores measured by the Modified Yale Preoperative Anxiety Scale (m-YPAS) and fear scores measured by the Fear Scale.

Based on a two-tailed independent samples non-parametric test (Wilcoxon-Mann-Whitney test for two independent groups), the statistical power analysis was conducted with the following parameters:

- **Effect Size (d):** 0.80 (Large effect size)
- **Alpha (α) Error Probability:** 0.05
- **Power (1- β Error Probability):** 0.80
- **Allocation Ratio (N2/N1):** 1.0

According to these parameters, the minimum required sample size to detect a statistically significant difference between the intervention and control groups was calculated as 54 participants in total (with 18 participants in each group). To compensate for potential dropouts, losses to follow-up, or incomplete data sheets, the final enrollment target will be adjusted accordingly by adding approximately 10-20% to the total sample size.

2. Statistical Analysis Methodology

All statistical analyses will be performed using Statistical Package for the Social Sciences (SPSS) software. The significance level for all statistical tests will be set at .

2.1 Descriptive Statistics

- Continuous variables (e.g., age, physiological parameters like heart rate, SpO2, blood pressure, and scale scores) will be expressed as mean standard deviation (), median, minimum, and maximum values.
- Categorical variables (e.g., gender, previous surgical history, chronic disease status, and parents' educational/occupational background) will be presented as frequencies () and percentages ().

2.2 Normality Testing

Before conducting comparative analyses, the distribution of continuous variables will be evaluated using normality tests (Kolmogorov-Smirnov or Shapiro-Wilk tests) alongside visual inspections of histograms and Q-Q plots.

2.3 Hypothesis Testing & Group Comparisons

- **Homogeneity Analysis:** Base demographic and clinical characteristics will be compared between the intervention (cartoon/mobile game) and control groups to ensure baseline homogeneity. Chi-square tests (or Fisher's exact tests) will be used for categorical data, and independent samples t-tests (or Mann-Whitney U tests) will be used for continuous data.
- **Primary Outcome Analysis (Anxiety and Fear Scores):** * To compare the post-intervention scores between the independent groups, the **Mann-Whitney U test** (or Independent Samples t-test, depending on normality) will be utilized.
 - To evaluate the changes within the same group from pre-procedure (baseline) to post-intervention, the Wilcoxon Signed-Ranks test (or Paired Samples t-test) will be used.
- **Physiological Parameters:** Pre- and post-intervention vital signs (pulse rate, blood pressure,) will be evaluated using repeated measures analysis or appropriate parametric/non-parametric tests to determine the physiological impacts of the intervention.

