Research protocol

1. Research background

In the therapeutic landscape of congenital heart disease (CHD), traditional pain management focuses primarily on pharmacotherapy, particularly in postoperative pain management. This usually includes the use of opioids and NSAIDs to reduce pain in children. However, these drugs often carry adverse reactions and side effects, especially in pediatric children, such as respiratory depression, dependence, digestive discomfort, etc. Additionally, pharmacotherapy may not fully address all aspects of postoperative pain management, especially in terms of emotional and psychological coping strategies. In terms of non-pharmacological care interventions, there have been some studies that suggest that environmental control, physiotherapy (e.g., massage and hot and cold therapy), cognitive behavioural therapy, relaxation training, and other psychosocial interventions may have a positive effect on reducing postoperative pain. These methods are often seen as adjunctive treatments and are used to complement traditional pharmacotherapy. Currently, non-pharmacological pain management in children with congenital heart disease is understudied, and there are no clear, evidence-based guidelines or protocols. In particular, the long-term effects and safety of various non-pharmacological interventions, and the effectiveness and feasibility of these interventions in different age groups and different types of CHD. There is a lack of large-scale, systematic clinical trials to validate the specific effects of these non-pharmacological approaches on pain management after pediatric cardiac surgery, particularly the long-term effects, improved quality of life, and psychosocial effects compared to conventional medical treatments. In addition, there is a lack of research on individualised interventions, i.e., how non-pharmacological interventions can be tailored to each child's specific situation.

2. Purpose of the study As an emerging pain management method, non-pharmacological nursing intervention has received increasing attention worldwide, especially after cardiac surgery in children, and the cartoon-based nurse-patient interaction model has not been confirmed to be effective in postoperative analgesia in children with CHD. In this study, a cartoon-based nurse-patient interaction model was applied as a non-pharmacological pain relief method for preschool children after CHD, and its effect was observed to provide a basis for the management of postoperative pain in clinical children. The significance of the study is as follows: (1) Improve pain management effect: This study will verify whether the cartoon-based nurse-patient interaction model can effectively reduce the pain after CHD in children and improve their comfort and satisfaction, which will provide a new clinical basis for improving the

postoperative pain management practice of clinical children. (2) Optimization of treatment plans: The study will explore whether cartoon-based nurse-patient interaction models can help improve children's treatment adherence, reduce complications, stabilize hemodynamic indicators (children's heart rate, blood pressure, respiratory rate, oxygen saturation, arterial blood gases), and shorten hospital stay. These are important indicators for evaluating the merits and demerits of drug labor pain treatment regimens, and have important reference value for optimizing the treatment plan for heart disease in children. (3) Improve the psychological state of family members: The psychological state of the parents of the child directly affects the rehabilitation process of the child and the overall health of the family. Non-pharmacological nursing intervention - cartoon-based nurse-patient interaction model can effectively improve the psychological state of parents and help improve parent satisfaction. (4) Improving the quality of care: This study will also evaluate the impact of non-pharmacological nursing interventions, cartoon-based nurse-patient interaction models, on the quality of caregiver work, and explore how to improve the quality of nursing services through these interventions, thereby improving the overall satisfaction of children and caregivers. Overall, this study will not only help enrich and expand the scientific research data on the nurse-patient interaction pattern of non-pharmacological nursing intervention-cartoons, but also provide new perspectives and methods for clinical practice, especially in the special population of pediatric CHD. Through the method of empirical research, the progress of knowledge and the improvement of practice in related fields should be promoted.

3. Research design types, principles and test steps

1. Study design 1. Study design: Interventional controlled study.

2. Research Methodology:

2.1 Research subjects Children who underwent CHD surgery in the Children's Cardiac Intensive Care Unit (CCU) of Beijing Children's Hospital Affiliated to Capital Medical University from June 2024 to November 2024 were selected according to the convenient sampling method. 2.2 Grouping methodology: To ensure the ethics of the study and the feasibility of implementation. In view of the moral and interference that may arise between different non-pharmacological interventions in two groups of children in a practical clinical setting, affecting the emotions of children and health care providers, this study will adopt a phased control approach. Children in June-July 2024 were the control group and the intervention group in October-November 2024.

2.3 Sample size calculation In this study, the sample size calculation formula $N1=N2=2\times[(Z\alpha+Z\beta)\sigma/\ \delta]^2$ was used to estimate the sample size using the Wong-Baker scale score

as the main utility index. Consulting relevant literature [101], it was found that σ=0.91, δ =0.47, the test level was α=0.05 (two-sided), the grasp was β=0.1, and the t-cut-off value table showed Zα=1.96 and Zβ=1.282. Considering the loss to follow-up of the samples during the study, the calculated sample size was increased by 10%, and finally N ≈86 was obtained, with 43 cases in each of the intervention and control groups.

2.4 Ethical principles When the sample is selected, the participants use the informed consent form to explain the purpose of the study, the process, and the version number: 1.1 Version date: 2024.7.11 4 The data collection method and the procedures of the study inform the parents of the children that this study will not cause physical or mental harm to the children and themselves, and the parents of the participants are requested to decide whether to participate in the study or not. Participants voluntarily participate and can withdraw at any time, and withdrawal has no impact on subsequent normal treatment and care. Effectively protect the privacy, respect, informed consent and other rights and interests of research subjects, and strictly keep all information obtained by participants strictly confidential. All aspects of the evaluation process will follow a standardized process to ensure consistency and accuracy in data collection. To ensure the accuracy and reliability of the information, participant feedback will be collected in a confidential environment, and the assessment process will avoid any suggestions or preconceived notions that could lead the participant to ensure their comfort and the authenticity of their responses. Additionally, we will regularly review data collection and management processes to identify and address potential issues, ensuring the reliability and validity of the study.

2.5 Intervention methods

2.5.1 Control group:

2.5.1.1 Paramedics: Composed of 30 female caregivers aged between 23 and 40 years who have previously received training in the standard of care for the relevant surgical perioperative but have not yet been specially trained in the non-pharmacological intervention-cartoon nurse-patient interaction mode.

2.5.1.2 Preoperative care: The responsible nurse introduces the hospital room environment and preoperative preparation to the child and parents, and the child and parents are familiar with the environment and the preoperative preparation process. The responsible nurse is always available to answer questions.

2.5.1.3 Postoperative routine care: including monitoring of vital signs, maintaining the acid-base balance of water and electrolytes, lung care, pipeline care, basic care, etc.

2.5.1.4 Postoperative pain management: (1) Pain assessment: First, the caregiver will

evaluate the child's pain level regularly (every 4 hours) using the Child Pain Rating Scale (Wong-Baker scale). (2) Non-pharmacological management of pain: When the child cries due to pain, the caregiver uses conventional non-pharmacological intervention and comfort methods such as hugging, coaxing, and touching. (3) Pain drug management: 1~3 days after surgery: pain is most severe within 24~72 hours after surgery, and may last for several days or weeks in some children. Children are routinely given oral or intravenous analgesics after surgery, usually for 3 consecutive days (see table 4 for details). Table 4 Analgesic usage and dosage Version number: 1.1 Version date: 2024.7.11 5 Type Usage Interval Time Maximum daily dose Ibuprofen suspension Orally 4-6 h within 24 hours no more than 4 1-3 years old, weight 10-15kg, 4ml 4-6 years old, body weight 16-21kg, 5ml 7-9 years old, body weight 22-27kg, 8ml ibuprofen injection once (6 months to less than 12 years old) Intravenous infusion 10mg/kg 4-6 h 2.4g or 40mg/kg (whichever is lower)) Maximum single dose 400mg Before administration, it must be diluted, concentration ≤ 4mg/ml acetaminophen oral suspension orally 4-6 hours within 24 hours no more than 4 1-3 years old, weight 12-15kg, once 3ml 4-6 years old, body weight 16-21kg, once 5ml 7-9 years old, weight 22-27kg, once 8ml After 3 days of surgery: can be administered as needed according to the results of pain assessment. Pharmacological treatment is considered when the child presents with moderate to severe pain (Wong-Baker score ≥4) and non-pharmacological interventions do not provide adequate relief. Doctors will decide which drugs to use, including NSAIDs or weak opioids, based on the child's overall condition and the parent's opinion. Once the decision to use medication is made, the caregiver will administer it as directed and monitor the child's pain relief and any potential adverse drug reactions.

2.5.2 Intervention group:

2.5.2.1 Establish a research team: A total of 7 team members, including 1 nursing graduate tutor, 1 pediatric intensive care unit doctor, 1 pediatric intensive care unit nurse, 1 pediatric intensive care unit specialist nurse, 2 pediatric intensive care unit nurses, and 1 psychological counselor (the researcher himself). (1) Determine the team leader and responsibilities: The nursing graduate supervisor and researcher are responsible for the preliminary research of the study, literature review, literature screening, intervention plan formulation and training, schedule control arrangement, research quality control, personnel management, task allocation, coordination of various work, and final result analysis. (2) Clarify the responsibilities of group members: doctors are responsible for providing medical knowledge and answering medical questions raised by children and parents; The head nurse is responsible for guiding routine nursing-related work and assisting the principal investigator to control the overall research progress and quality of research. 1 specialist nurse recruited the children and

implemented the intervention; 2 nurses are responsible for the collection of clinical case data; 1 psychological counselor is responsible for participating in research and psychological guidance.

2.5.2.2 Intervention program training: Nursing is carried out by the same group of caregivers as the control group, but the researcher completes the implementation plan and data collection method training of the cartoon-based nurse-patient interaction model during the interval period before the intervention group implements the study.
2.5.2.3 Establishment of animation database: The research team established a database of animations before the implementation of the intervention group. First of all, a cartoon database is established based on the cartoons that most preschool children love, including "Bear Infestation", "Cute Chicken Squad", "PAW Patrol Achievements", "Peppa Pig", "Sheep and Gray Wolf", "SpongeBob SquarePants", "Pig Man", "My Little Pony", "Little Princess Sophia", "Undersea Column", "Tom and Jerry", "Bidden Rabbit", "Pig Man", "Super Wings Pan", "Milk Dragon", "Elf Dream Ye Luoli", etc., these vivid and interesting cartoons can have a benign effect on the mood and condition of the child. Download it to your phone or iPad.

2.5.3 Pre-trial In September 2024, 5 children with CHD who met the criteria for inclusion were selected at Beijing Children's Hospital Affiliated to Capital Medical University for pre-experiment to observe the feasibility of the intervention method.

3. Research period 2024.8.1-2024.12.31

4. Subject selection Inclusion criteria: (1) According to the "Guidelines for the Diagnosis and Treatment of CHD in Children" and cardiac ultrasound imaging [100]Children diagnosed with CHD for surgical treatment; (2) Age 3~7 years old, including 3 and 7 years old; (3) The surgical method is thoracotomy; (4) Diagnosis of ventricular septal defect, atrial septal defect or atrial septal defect combined with ventricular septal defect, patent ductus arteriosus, tetralogy of Fallot; Exclusion criteria: (1) Those with obvious abnormal cardiovascular lung, liver and kidney function, other chronic diseases, neuropsychiatric diseases, and malignant tumors; (2) Congenital heart disease combined with other organ malformations; (3) taking sedatives and antidepressants; (3) Those with intellectual disability, developmental delay, or behavioral disorder; (4) Hearing and communication impairments in children; (5) Parents of children with mental retardation or mental illness; Removal criteria: (1) Extubation cannot be done after surgery; (2) Unplanned reoperation 48 hours after surgery; (3) Unable to communicate normally due to impaired consciousness or changes in condition after surgery; (4) Those who stop treatment due to other reasons such as transfer to hospital, department or death midway. (5) Children and their families choose to withdraw from the study midway for

various reasons.

4. Research methods

4.1 Implementation of the intervention program

4.1.1 Preoperative care: The children in the intervention group completed the following preoperative interactions on the basis of the preoperative routine care in the control group. (1) Choose cartoons: Because each age group or even 1 year apart children like different cartoons, and considering the different personality and psychological characteristics of children, each child likes different cartoons. When using cartoons, it is difficult to ensure that cartoons are at the same level of attraction to children and that every child's attention is devoted to the cartoon. Therefore, the caregiver determines the favorite cartoon of each child before surgery. The preoperative nurse in charge and the parents of the child to understand the children's favorite cartoons, and together with the family members, let the children choose 3 favorite cartoons in the cartoon database, and the responsible nurse will record the names selected for postoperative application. (2) Interaction between the nurse and the child: take the child as the leader, communicate with the child before surgery, and the responsible nurse patiently guides the child to raise his or her concerns about the operation, and uses easy-to-understand friend-style communication to alleviate the child's anxiety and fear of surgery. (3) Interaction between nurses and parents: The responsible nurse distributes the "Disease Manual", which details the pathogenesis, symptoms, treatment, surgical steps and postoperative precautions. In order to reduce the anxiety of parents of children and allow parents to fully express their psychological state before surgery and their worries about surgery, the nurse answered the parents' questions and concerns in detail. The responsible nurse and parents discuss specific measures for postoperative care, and affirm and encourage the active participation of parents. (4) Parent-child interaction: Teach parents how to interact with children. Parents can use positive language to guide and encourage their children to face and receive surgery. Reduce the impact of parents' anxiety about the child's surgery, face the child with a smile, hug the child, and choose cartoons to watch before and after the operation.

4.1.2 Postoperative routine care: After returning to the CCU to remove the endotracheal tube, the children will receive routine postoperative care in the control group.

4.1.3 Postoperative pain management: On the basis of postoperative pain management in the control group, the responsible nurse uses a mobile phone or Ipad to play the cartoons selected by the child before surgery according to the child's choice, and can watch the cartoon throughout the whole process or according to the child's wishes after waking up after the operation, and the volume of the device is adjusted to a comfortable

level, each cartoon does not exceed 30 minutes, 3~6 times a day, to distract attention and let the child's eyes rest to protect vision. Nurses can also discuss the plot with the child, mobilize the child's subjective initiative, gain their trust, and change from passive participation to active participation.

5. Concomitant medication None

6. Observation indicators General information, physiological indicators, postoperative complications, pain assessment, children's anxiety assessment (mYPAS score), anxiety assessment, parent satisfaction.

7. Pre-assessment of project risks and risk disposal plan In this study, the use of electronic products such as mobile phones or IPAPs may cause visual fatigue and dependence in children.

8. Quality control and quality assurance of research The quality control and supervision of research are explained from the aspects of laboratory index testing, implementation of relevant SOPs, researcher training, subject compliance, and research monitoring.

8.1 Researcher training Nursing is carried out by the same group of caregivers as the control group, but before the intervention group implements the study, the researcher completes the implementation plan and data collection method training of the cartoon-based nurse-patient interaction model during the interval.

8.2 Subject compliance Before participating in the trial, the investigator should explain the potential risks of using this study to all subject guardians and inform the subjects that cooperating with the safety monitoring required in the trial protocol can minimize the risks.

9. Data preservation The collected research data is entered on the same day, and the researcher enters it by one person, with double data entry and regular data cleaning to minimize human error. At the same time, use a secure, encrypted electronic data system to protect participant information.

10. Data security monitoring All collected data will be stored and analyzed uniformly to strictly protect the privacy of participants. To ensure the accuracy of the data and the reliability of the research, we will also conduct regular audits of data quality. All reviews and entries are entered by the researcher into the same computer electronic data record form file. All questionnaires are collected and checked by the survey staff on the spot, and after the survey, the researcher reviews the collected questionnaires and eliminates invalid questionnaires.

11. Statistical processing The data were entered by excel2023 software and a database

was established, and SPSS29.0 was used to perform statistical analysis on the data. The data that meet the normal distribution are expressed by mean ± standard deviation, and the data that do not meet the normal distribution are statistically described by the median and interquartile spacing M (IQR). The counting data are described by composition ratio and percentage. For statistical inference, paired t-tests were used for intra-group comparisons of normally distributed and homogeneous variance, and two-sample t-tests were used for comparisons between groups. The correction t-test is used for uneven variance; The counting data were tested by chi-square. All statistical tests were two-tailed tests, with a $P<0.05$ indicating that the difference was statistically significant.

Informed Notice

Dear Parents, We invite your child to participate in the study approved by Beijing Children's Hospital Affiliated to Capital Medical University on the effect of animated nurse-patient interaction model on postoperative pain in children with congenital heart disease. This study complies with the Declaration of Helsinki, clinical trial quality management practices, and ethical review, and has been reviewed by the Medical Ethics Committee of Beijing Children's Hospital Affiliated to Capital Medical University. Before you decide whether your child will take part in this study, read the following as carefully as possible. He can help you understand the study and why it is being conducted, the procedure and duration of the study, the benefits, risks and discomfort that may be brought to you after participating in the study. If you wish, you can also discuss it with your relatives and friends to help you make a decision.

1. **What is the purpose of clinical research?** Due to the particularity of cardiac surgery itself, the requirements for postoperative analgesia in children are also higher, and there is a lot of room for improvement in analgesia schemes that need to be explored urgently. A literature review shows that watching cartoons can be a good distraction for children and may improve their anxiety and adherence, but there have been no studies on the application of cartoon interventions to postoperative analgesia for congenital heart disease in preschool children. Therefore, this study applies the animation-based nurse-patient interaction model as a non-pharmacological analgesic method to observe the effect of analgesic sedation on preschool children after congenital heart disease, and provides clinical theoretical support for clinical intervention for postoperative pain in children with heart disease.

2. How many children will take part in the study? Approximately 7 0 subjects will participate in this study.

3. **How long will this study last?** The overall study duration is 4 months, and the duration of each subject's participation in the study is about 2-3 days.

4. What does this study include? This study is an interventional study, which requires study samples, questionnaires, pain score scales, anxiety tables, satisfaction surveys, etc. Your child will undergo the following tests and procedures to further confirm whether your child is suitable for this study: Version Number: 3 .1 Version Date: 2025.05.08 3 / 6. •Physical examination and medical history query; •important signs (such as respiration, body temperature, heart rate, etc.); •An ECG used to record electrophysiological activity of the heart. This study will compare the effects of routine pain care after congenital heart disease and the use of cartoon nurse-patient interaction mode on postoperative

pain in children with congenital heart disease. It does not contain any drugs and does not collect blood. Then compare whether the cartoon is effective in reducing postoperative pain. Throughout the study, we will collect your child's response to the study and your child's health through a series of indications and scores.

5. What treatments will your child receive if they participate in the study? If you are willing to participate in this study and your child is eligible for enrollment, your child will be randomly assigned to any group for treatment and will receive the following treatment regimens: Control group: Oral or intravenous ibuprofen analgesics will be given 1-3 days after surgery according to the usual care after congenital heart disease; Intervention group: In addition to the usual care after congenital heart disease, followed by watching cartoons as the treatment, we will regularly rate your child after the endotracheal tube is removed and within 2-3 days after the operation, and reduce the frequency of painkillers. Pain score time: After the child returned to the CCU for endotracheal intubation and 24 hours and 48 hours after surgery. Generally, after waking up after surgery, you can watch cartoons throughout the whole process or according to your child's wishes, and adjust the volume of the device to a comfortable level, no more than 30 minutes per cartoon, 3~6 times a day, to distract attention and let the eyes rest to protect vision. In the above treatment, watching cartoons is an investigational treatment (i.e. if you do not participate in this study, your child does not need to receive that treatment).

6. Who will be selected for the study? Criteria for enrollment Diagnosis of congenital heart disease; Age 3~7 years, including 3 and 7 years old; The surgical method is thoracotomy; Time of endotracheal intubation: Children who had their endotracheal intubation removed on the day of returning to CCU after surgery; The diagnosis is ventricular septal defect, atrial septal defect or atrial septal defect combined with ventricular septal defect, patent ductus arteriosus, tetralogy of Fallot, and vascular ring. Whether your child can participate in the study needs to be decided after a doctor's examination.

7. Who should not participate in the study? Exclusion criteria (1) Those with obvious abnormalities in cardiovascular and lung liver and kidney function, other chronic diseases, neuropsychiatric diseases, and malignant tumors; (2) Congenital heart disease combined with other organ malformations; (3) taking sedatives and antidepressants; (3) Those with intellectual disability, developmental delay, or behavioral disorder; (4) Hearing and communication impairments in children; (5) Version number: 3.1 Version date: 2025.05.08 4 / 6 Parents with mental retardation or mental illness.

8. What are the risks or discomforts of participating in the study? All treatments have

the potential for side effects. Due to the mobile phones, iPads, and other electronic products used in this study protocol, children may experience discomfort such as eye strain. We will take different plans in time according to the child's condition, reasonably control the use time, and reduce the child's visual fatigue and other discomforts. If you have any questions, please consult your doctor or nurse.

9. What are the benefits of participating in research? Your child's condition may or may not improve by participating in this study, and it is possible that you will be able to reduce postoperative heart pain and the frequency of pain medication use.

10. Do I need to pay for participating in the study? This study provides an animated intervention for your child's postoperative pain free of charge and does not require additional costs. However, you need to pay for normal surgery, diagnosis and treatment.

11. Are there any subsidies for participating in research? You or your child will not be compensated for participating in this study.

12. What happens if your child is impaired while participating in the study? If your child does develop study-related impairments as a result of participating in this study, please notify the study doctor immediately and they will be responsible for administering appropriate treatment to your child. If damage is caused by research, the researcher will bear the treatment cost and give corresponding economic compensation in accordance with relevant national regulations. Even if you have signed this informed consent form, you still retain all your legal rights.

13. How will the study process your child's sample/data? Samples of your child's pain scores will be taken during the study for pain analysis and for postoperative pain in congenital heart disease. The biological samples collected in this study were tested and stored in the hospital and did not require discharge. After the study, any remaining pain score samples belonging to your child will be destroyed.

14. Is your child's personal information confidential? Your child's medical records will be kept in the hospital, and the investigators, study authorities, and ethics committees will be allowed to access your child's medical records. Any public reporting of the results of this study will not disclose your or your child's personal identity. We will make every effort to protect the privacy of your child's personal medical information to the extent permitted by law. **1**

5. Does your child have to take part in the study? Participation in this study is completely voluntary, and you may refuse to participate in the study, or withdraw from this study at any time during the course of the study without any reason. This decision will not affect the doctor's treatment of your child. If you decide to withdraw from this

study, please contact your doctor in advance. To keep your child safe, your child may be asked to undergo some relevant tests, which is beneficial to protect your child's health. In addition, your child may withdraw from the trial for any of the following reasons: 1) withdrawal from the study for any reason (withdrawal of informed consent) 2) inclusion of a condition that does not meet the inclusion criteria (emerging or previously undiscovered) 3) the study doctor determines that withdrawal from the trial is in the best interest of your child's health and welfare or consideration of your child's condition

16. How can I get more information? If you have any questions related to your own rights and interests, or if you want to reflect your dissatisfaction and concerns in the process of participating in this study, please contact the Medical Ethics Committee of Beijing Children's Hospital at email: bch_irb@163.com, telephone: 59616083.

Project Title: Study on the effect of cartoon nurse-patient interaction model on postoperative pain in children with congenital heart disease

Subject Statement: I have read the above introduction about this study and I am volunteering to participate in this study. I am fully aware of: 1. The risks and benefits that may arise from participating in this study. 2. I can consult the doctor for more information at any time. 3. My child can withdraw from this study at any time without discrimination or retaliation, and medical treatment and rights will not be affected.

Consent Signature Page

Participant's Full Name in Block Letters:

Parents/Legal Guardian's Full Name in Block Letters:

Contact Phone Number:

Statistical processing

The data was entered by two people using Excel 2023 software and a database was established. SPSS 29.0 was used to perform statistical analysis on the data. For measurement data, a normality test (Kolmogorov-Smirnov test) was first conducted. Data that conformed to a normal distribution was expressed as mean ± standard deviation, and data that did not conform to a normal distribution was statistically described using the median and interquartile range M(IQR); for count data, the constituent ratio and percentage were used for description. During statistical inference, for measurement data that conformed to a normal distribution and had homogeneous variances, paired t-tests were used for within-group comparisons, and two independent sample t-tests were used for between-group comparisons; for heterogeneous variances, corrected t-tests were used; for count data, chi-square tests were used. All statistical tests were two-sided tests, and a $P < 0.05$ was considered statistically sig