

Informed Consent Form for Clinical Research Projects

Scheme Name: Application of Improved Clown Care in Nebulization Inhalation Nursing in Pediatric Outpatient Clinics

Scheme Version Number and Date: 4.0, March 21, 2025

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Research Institution: The First Affiliated Hospital of Zhejiang University

Principal Investigator: Wu Jun

Subject Name:

Subject Name Abbreviation:

Subject address:

Subject's phone number:

We would like to invite you to participate in a clinical study. This informed consent form provides you with some information to help you decide whether to enroll in this clinical study. Please take the time to read the following information carefully. If you have any questions or unclear terms, feel free to discuss them with your physician.

Your participation in this study is entirely voluntary. This study has been reviewed and approved by the hospital's IIT Ethics Review Committee.

Research Background: Medical clowns, also known as clown therapy, utilize professionally designed humorous performances and creatively engaging interactions to effectively alleviate the tension and anxiety that patients experience due to illness. By creating a relatively relaxed and joyful atmosphere during medical procedures, clown therapy enhances the patient's experience in clinical care settings. Clown therapy has been extensively studied in pediatrics and is widely applied in pediatric perioperative care, intravenous catheter placement, burn wound dressing changes, and other medical procedures. It has proven effective in reducing children's anxiety and pain levels, thereby improving their compliance with clinical care procedures.

Children with pneumonia often feel unfamiliar and frightened by nebulizer inhalation devices, frequently crying uncontrollably and resisting wearing the mask, which makes it difficult to start treatment smoothly. During treatment, some children also struggle to remain still for long periods, frequently twisting their bodies, which prevents the nebulized medication from being accurately delivered to the lung lesions and thus compromises the effectiveness of the therapy. Therefore, enhancing children's compliance

with nebulization therapy and alleviating their anxiety and pain are crucial aspects of pediatric nursing care.

Research Objective:

To explore whether the introduction of clown therapy in nebulizer inhalation treatment in pediatric outpatient clinics can reduce children's anxiety and pain levels, alleviate family members' anxiety, and improve children's treatment adherence and therapeutic outcomes.

Research process:

Our study aims primarily to determine whether improved clown care can help children like your child who are receiving nebulizer treatments in the pediatric outpatient clinic. The study will recruit 100 to 200 children aged 2 to 10 years who are undergoing nebulizer therapy for the first time or within the past year, and who have come to the clinic for treatment due to upper or lower respiratory tract infections. These children must be fully conscious, with normal cognitive, visual, and auditory functions, and must be under the continuous care of the same team of doctors and nurses throughout their diagnosis and treatment. Children with cognitive impairments, congenital developmental disorders, allergies to nebulizer medications, severe pneumonia complicated by respiratory failure, or dysfunction of other organs such as the heart, liver, or kidneys, as well as those who are taking other long-term medications in addition to those prescribed for their respiratory infections, will not be eligible to participate in this study.

During the study, your child will be randomly assigned to one of two groups. The assignment is determined by a computer program, and neither you nor the doctor can choose which group your child is assigned to—this ensures fairness. Your child has a 50% chance of being assigned to the clown therapy group and a 50% chance of being assigned to the control group.

If your child is assigned to the clown therapy group, when you bring your child in for treatment, the doctor and nurse will first introduce you to the enhanced clown medical service. Once you give your consent, they'll tailor the interaction approach based on your child's personality traits and ask you to sign an informed consent form. Then, a clown volunteer will accompany your child into the nebulizer treatment room. Before the treatment begins, the clown volunteer will engage with your child, play games, and help ease any fear or anxiety your child might feel. Five minutes before the nebulization starts, the clown volunteer will continue playing with your child—dancing fun bear dances, performing magic tricks, and even imitating funny gestures while wearing the nebulizer mask—to build a sense of familiarity and trust between the clown and your child. After the nebulization is complete, the clown volunteer will reward your child with a buttery teddy bear sticker. If your child successfully completes the nebulization treatment course for 2–

3 consecutive days, the clown volunteer will also present an additional small toy as extra encouragement to keep your child cooperating with subsequent treatments.

If you're assigned to the control group, you'll receive standard care. During nebulizer treatments, doctors and nurses will use verbal communication and gestures to comfort the child, depending on how well the child cooperates.

During the study, you'll need to cooperate with us in several ways. Each time your child comes for nebulizer therapy—specifically, at the very first session of the day—our medical staff will assess both you and your child. Over the course of the 2- to 3-day treatment period, we'll carry out approximately 2 to 3 assessments in total. These assessments primarily involve using questionnaires to gather information about your child's condition, for example, how your child behaves during nebulizer treatments: whether they actively cooperate or show some resistance. We'll also ask about your feelings as a parent, such as your level of anxiety during your child's nebulizer sessions. These questionnaire-based assessments won't require your child to undergo any additional tests or examinations.

Please rest assured—this entire research process is designed to help children like your child better accept nebulizer therapy, and we will do our utmost to safeguard both your rights and your child's rights.

Risks and Discomforts of Participating in the Study:

In this study, the use of modified clown-assisted nebulization therapy may lead to the following conditions:

Very common (incidence $\geq 10\%$)

■ Risk: The child may experience mood swings and excessive excitement. For example, during interactions with the clown, the child might become overly excited and find it difficult to calm down.

■ Handling Measures: If this situation occurs, medical staff will immediately comfort the child with gentle words—such as speaking softly to the child or telling them a story. They will also adjust the way the clown interacts with the child, for example, by reducing some of the more vigorous performance segments to make the interaction more soothing and help the child calm down as quickly as possible.

Common (incidence $>1\%$ — $<10\%$)

■ Risk: It may cause social pressure for introverted children. For example, an introverted child might feel tense and uneasy when interacting with a clown due to unfamiliarity and discomfort.

■ Handling Measures: Once healthcare staff notice such behavior in a child, they will temporarily suspend clown-assisted interventions and arrange for professional psychological counselors to communicate with the child and provide psychological support. After the child's emotions have stabilized somewhat, they will reassess whether to continue the clown-assisted interactions.

Uncommon (incidence >0.1%—<1%)

■ Risk: Some family members may experience feelings of worry, tension, and anxiety—for example, concern that clown care might have negative effects on the child.

■ Handling Measures: Medical staff will promptly communicate with family members, patiently answer their questions, and provide detailed explanations about the purpose, methods, and safety of clown therapy, ensuring that family members fully understand the entire process and helping them alleviate these negative emotions. Rare (incidence <0.1%)

■ Cardiovascular and cerebrovascular risks caused by emotional arousal;

■ Risk: The child may experience cardiovascular and cerebrovascular risks due to emotional excitement, though the likelihood of this occurring is extremely low.

■ Treatment Measures: As soon as a case occurs, medical personnel at the scene will immediately activate the emergency medical rescue protocol and provide treatment to the child according to the hospital's professional first-aid procedures, doing their utmost to ensure the child's safety.

Unknown risks: There may be some risks and adverse reactions that cannot be predicted at this time.

■ Treatment Measures: If this situation arises, our medical team will closely monitor the child's condition and, based on the specific symptoms the child is experiencing, adopt the most appropriate treatment and management approach. We will also keep you promptly informed about the child's condition.

You should know that your child may not experience any adverse reactions at all. Even if they do occur, the severity will range from mild to moderate or severe. Regardless of the situation, our doctors and nursing team will immediately provide your child with appropriate symptomatic treatment—so there's no need for you to worry excessively. You may experience no adverse reactions at all, or only some mild, moderate, or severe adverse reactions. If any of the above-mentioned adverse events occur, your doctor and nursing team will provide you with active symptomatic treatment.

Benefits of participating in the study:

If you agree to participate in this study, you will not receive any direct medical benefits.

Alternative therapy:

In addition to participating in this study, you have the following options:

■ Only standard nebulization therapy is provided: Under this arrangement, when your child receives nebulization treatment, there will be no clown care providing interactive companionship. Instead, medical staff will follow the standard nursing procedures and offer verbal and physical reassurance based on your child's response to the nebulization.

Please discuss these and other possible options thoroughly with your doctor to make the decision that's best for your child.

Relevant costs for participation in the study:

The dolls used in the modified clown therapy—providing companionship, performing shows, and using performance props—as well as the small toys given at the end of the therapy session are all provided free of charge. Oral medications prescribed by the pediatric outpatient clinic, medications for nebulizer inhalation, and medical procedures will be billed according to standard clinical fees.

Compensation:

No compensation is provided for participating in the trial.

Compensation:

We have purchased clinical trial liability insurance for this study, which covers adverse reactions or damages directly related to the trial (for specific coverage details, please consult the investigator or review the terms of the insurance contract). If a subject experiences an adverse reaction or damage related to the study and such incident falls within the scope of insurance coverage, compensation will be provided in accordance with the provisions of the insurance contract. For damages related to the trial that are not covered by the insurance, the sponsor will bear the necessary medical treatment costs and provide reasonable financial compensation, as stipulated by relevant laws and regulations such as the "Good Clinical Practice for Drug Clinical Trials" and the "Civil Code." Damages resulting from the subject's failure to disclose pre-existing medical history or violation of the study protocol, aggravation of pre-existing conditions unrelated to the study, force majeure events, or damages caused by third-party liability are excluded from coverage.

The right to refuse to participate in or withdraw from the study:

You may choose not to participate in this study, or you have the right to withdraw at any stage of the trial without providing any reason. Your medical care and rights will not be

affected in any way as a result of your decision. Once you decide to participate in this study, please sign this informed consent form to indicate your agreement. Before entering the study, your physician will conduct a screening to determine whether you are an eligible candidate.

Privacy and Confidentiality Issues:

During the study, your personal information—such as your name and gender—will be replaced with a code or number and kept strictly confidential. Only the relevant physicians will have access to your data, ensuring that your privacy is well protected. The study results may be published in a journal, but no personal information about you will be disclosed.

If you agree to participate in this study, your relevant medical records will be reviewed by personnel from the research and development organization initiating this study, by relevant authorities, or by the independent hospital's IIT Review Committee, to ensure that the study's procedures are conducted appropriately. By signing the informed consent form, you signify your agreement to allow these individuals to access your medical records.

How to obtain assistance in the study:

You can stay informed about information and research progress related to this study at any time. If you have any questions regarding this study, please contact Wu Jun (researcher or relevant staff member) at 13738138313 (phone number). Contact information for the Hospital's IIT Ethics Review Committee: No. 79 Qingchun Road, Shangcheng District, Hangzhou City, Zhejiang Province; 0571-87233418.

Informed Consent Signature – Consent Form (for patients aged 8–10)

If you fully understand the contents of this research project and agree to participate in the study, you will sign this informed consent form in duplicate, with one copy retained by the researcher and the other by the subject's guardian.

Clinical Study Project Title: Application of Modified Clown Care in Nebulizer Inhalation Nursing in Pediatric Outpatient Clinics.

Signed by the subject themselves and their guardian:

Consent Statement:

1. I confirm that I have read and understood the informed consent form for this study, that I have been explained the potential issues that may arise during the study and their corresponding solutions, and that I have had the opportunity to ask any questions I might have.
2. I have clearly understood that participation in the study is voluntary, and refusing to participate will not impair any of my legitimate rights or interests.
3. I have been informed that the physicians involved in this study, the person in charge at the First Affiliated Hospital of Zhejiang University who is overseeing this work, and the hospital's IIT Ethics Review Committee all have the right to review the study records and case data. I agree that the aforementioned individuals may directly access my study records and understand that the information they obtain will be kept confidential.
4. I agree to participate in this study.

Subject's signature:

Date:

Subject's contact information:

Guardian's Signature:

Date:

Guardian's contact information:

Relationship between guardian and subject:

Researcher's Signature:

Date:

Researcher Contact Information:

Informed Consent Signature – Consent Form (for children aged 2-8)

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Signed by the subject's guardian:

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Guardian's Signature:

Date:

Guardian contact information:

Relationship between guardian and subject:

Researcher's Signature:

Date:

Researcher Contact Information: