The Application of Family-Participatory Care Based on Swanson's Caring Theory in Premature Infants

Informed Consent Form - Informed Disclosure Page

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Dear MR./MRs. ,

We will invite you to participate in a single-center cohort study titled "Application of Family-Involved Care Based on Swanson's Theory of Caring in Premature Infants", aiming to explore the application of the FICare theory based on Swanson's caring theory in the care of premature infants.

Before you decide whether to participate in this research, please read the following content as carefully as possible. It can help you understand the research, the reasons for conducting it, the procedures and duration, as well as the potential benefits, risks and discomforts that may result from your participation. If you wish, you can also discuss it with your relatives and friends or ask your doctor to explain it to help you make a decision.

Research Introduction

1. Background and Objectives

Premature infants refer to live-born neonates with a gestational age of less than 37 weeks. Common risk factors include infection or inflammation, uterine-placental ischemia or hemorrhage, excessive uterine distension, stress, and other immune-mediated processes. Globally, approximately 15 million premature infants are born each year, accounting for more than 10% of all newborns, and the number is on the rise. Due to the need for special care in the neonatal intensive care unit (NICU), premature infants have longer hospital stays and are separated from their parents, which studies show can cause anxiety for both parents and the newborns.

Family Integrated Care (FICare) aims to enhance the quality of care for premature infants, involve parents in decision-making, and provide parenting education and psychological support. The core of this approach lies in treating parents as the primary caregivers of their infants and involving them in the entire process from the birth to the hospitalization of the premature baby. NICU staff encourage parents to actively participate in the care of their infants and assume the roles of medical supervision and support. Swanson's Theory of Caring, proposed by Dr. Kristen M. Swanson, emphasizes the role of genuine connection in the nurse-patient relationship and guides nurses through five fundamental processes of holistic care: maintaining belief,

understanding, companionship, doing for, and enabling. The goal of this theory is to empower, sympathize with, and support patients throughout their recovery process.

Previous studies have shown that FICare in single-family rooms can reduce the risk of late-onset sepsis in preterm infants, shorten their hospital stay, lower the risk of readmission, and increase the rate of breastfeeding. However, the effect of FICare based on Swanson's caring theory on the growth and development of Chinese newborns and the anxiety state and parenting competence of their parents remains unclear. We conducted a cohort study to reveal this effect.

The ethics committee has reviewed and determined that this research adheres to the principles of the Declaration of Helsinki and is in line with medical ethics.

2. Who should not participate in the research?

2.1 Premature infants suffer from severe congenital and genetic diseases.

2.2 Premature infants have significant organ dysfunction and require mechanical life support.

2.3 Premature infants need surgical intervention.

2.4 Premature infants have a birth weight of less than 500g.

3. What will be required if one participates in the research?

3.1 Before you are selected for the study, you will undergo the following examinations to determine if you are eligible to participate in the research:

Vital signs of premature infants.

3.2 If you have completed the above information collection, the study will proceed as follows:

Record gestational age, gender, and during hospitalization, record the duration of oxygen therapy, length of hospital stay, and other hospitalization data. Before and after nursing, record the anxiety state score and parenting competence scale score of the parents. The premature infants will be followed up until the corrected age of 6 months, and at the corrected ages of 1, 3, and 6 months, record the head circumference, height, and weight information.

4. Possible adverse reactions, risks, discomforts and inconveniences of participating in the research.

This study was a cohort study. The control group received traditional care, while the study group received FICare care. There were no adverse reactions or risks. Follow-up was conducted by phone and at outpatient clinics, and there was no discomfort. It did not increase the risks during the care process of premature infants.

5. Is personal information kept confidential?

Your medical records (including medical history, laboratory test results, etc.) will be kept complete in the hospital. The doctor will record the test results in your outpatient medical record. Researchers or members of

the research team, the ethics committee, and the government department in charge of the project will be allowed to access your medical records. Any public reports on the results of this study will not disclose your personal identity. We will do our best to protect the privacy of your personal medical information within the scope permitted by law.

Apart from this study, your medical records and pathological examination specimens may be used again in other future studies. You can also declare now to refuse the use of your medical records and pathological specimens in other studies apart from this one.

6. How can I get more information?

You can raise any questions about this study at any time. Your doctor will leave you his/her phone number so as to answer your questions. If you have any complaints about participating in the study, please contact the hospital ethics committee office. If any important new information emerges during the study that may affect your willingness to continue participating, your doctor will inform you in a timely manner.

7. Participants can voluntarily choose to join the research and withdraw from it at any time.

Whether or not to participate in the research is entirely up to your own will. You can refuse to take part in this research or withdraw from it at any time during the process. This will not affect your relationship with your doctor, nor will it cause any loss to your medical treatment or other interests. Your doctor or the researcher may stop your participation in this research at any time for your best interests. You are not obliged to take part in this research.

8. What should be done now?

Whether to participate in this research is entirely up to you. You can discuss it with your family or friends before making a decision.

Before you decide to take part in the research, please ask your doctor as many questions as possible until you fully understand this research.

Thank you for reading the above materials.

If you decide to participate in this research, please tell your doctor or research assistant, and he/she will arrange everything related to the research for you.

Please keep this material.

Informed Consent Form - Signature Page for Agreement

Clinical research project title: Application of Family-Participatory Care Based on Swanson's Theory of Caring in Premature Infants

Clinical research conducting unit: Yongkang Maternal and Child Health Hospital

Consent Statement

I have read the above introduction about this research and had the opportunity to discuss it with the doctor and raise questions. All the questions I raised were answered satisfactorily.

I am aware of the potential risks and benefits of participating in this research. I understand that participation in the research is voluntary, and I confirm that I have had sufficient time to consider this and am aware that:

I I can consult the doctor for more information at any time.

II I can withdraw from this study at any time without discrimination or retaliation, and my medical treatment and rights will not be affected.

I am also well aware that if I withdraw from the research halfway, especially due to the side effects of the drug, it would be very beneficial for both myself and the entire research if I inform the doctor of my condition changes and complete the corresponding physical examination and laboratory tests.

If I need to take any other medication due to changes in my condition, I will seek the doctor's advice in advance or inform the doctor truthfully afterwards.

I agree that the ethics committee or representatives of the sponsor and the research quality inspectors may review my research materials.

I agree□ OR refuse□ Other studies, apart from this one, have utilized my medical records and pathological examination specimens.

I will receive a copy of the informed consent form that is signed and dated.

Finally, I decided to agree to participate in this research.

Signature of the subject: _____ ____ ____ ____Y ____ M ____ D

Contact number of the subject:_____ phone number:_____

Signature of legal representative (if any):_____ date:_____Y____M____D

I confirm that I have explained the details of this study to the patient, including their rights and the possible benefits and risks, and have given them a copy of the signed informed consent form.

Signature of the researcher:_____ Date：____ ____ ____ ____ Y____ ____M ____ ____ D

Researcher's work phone number:_____ phone number：_____