

Informed Consent Form (ICF)

Unique Protocol ID: JNU20221201IRB20

Official Title: Construction and Effect Evaluation of
Parent Infant Skin-to-Skin Contact Intervention
Program Based on The Co-parenting Theory

NCT05785806

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Informed Consent Form (ICF)

Dear Participants

You will be invited to participate in a clinical study of neonatal skin contact intervention based on co-parenting theory for both parents after cesarean section. This informed consent form provides you with some information. Before you decide whether to participate in this study, please read the following carefully as much as possible. It helps you understand the study and why it was conducted, the process and duration of the study, and the benefits, risks, and discomforts that may result from participating in the study. If you wish, you can also discuss it with your relatives and friends, or ask your doctor for an explanation to help you make a decision.

1. Research purpose

Objective : To explore the family-centered nursing model under the theory of co-parenting ; based on the theory of co-parenting, a neonatal skin contact program with the participation of both parents was constructed for the primipara family of cesarean section, and its effect was evaluated. Pay attention to the coordination and balance of postpartum family system, promote father 's participation in childrearing, attach importance to the value of parents as caring partners, and improve the ability of husband and wife to raise together.

2. Research introduction

Research Overview : This study will be conducted in the Obstetrics Department, Affiliated Hospital of Jiangnan University. The subjects volunteered to participate and were assigned to different groups according to the recruitment time.

This study has been approved by the Medical Ethics Committee of the Affiliated Hospital of Jiangnan University.

The Medical Ethics Committee of the Affiliated Hospital of Jiangnan University has approved that the study is in accordance with the principles of the Helsinki Declaration and in line with medical ethics.

Main research contents : Intervention contents :

- (1) Skin contact and co-parenting theory course ;
 - (2) Skin contact instruction manual, co-parenting theory brochure ;
 - (3) face-to-face guidance (daily) ;
 - (4) WeChat follow-up (both husband and wife) ;
- check operation : follow-up for three months, fill in the relevant scale

3. Who should not participate in the study

- (1) multiple pregnancy
 - (2) Pregnant women have serious complications / complications, such (3) as eclampsia, postpartum hemorrhage, severe cardiopulmonary dysfunction, etc.
 - (4) Prenatal examination of the fetus with chromosomal abnormalities or possible malformations
 - (5) One of the couple has mental retardation or mental disorders can not cooperate
 - (6) Delivery before 37 weeks of gestation
 - (7) Postpartum mother-to-child separation, newborns need to be treated and monitored in NICU
 - (8) Evaluation information collection is not perfect
4. What will be needed if participating in the study ?

Before you are enrolled in the study, the doctor will ask and record your medical history in detail. You are eligible for inclusion. You can volunteer to participate in the study and sign the informed consent. If you volunteer to participate in the study, the following steps will be followed : They will be grouped according to time for prenatal and postnatal intervention and follow-up after discharge.

5. Adverse reactions, risks and discomforts that may occur in the study

Not yet

6. Privacy of personal information and medical records

The records of your identity are confidential, and your name will not appear in case records, any relevant research reports, or public publications. Your medical records (study cases / CRF, laboratory sheets, etc.) will be completely stored in the hospital you visited. The doctor will record the test results on your inpatient or outpatient medical records. If necessary, only researchers, sponsors, supervisors, and ethics committees have access to all your research records. We will make every effort to protect the privacy of your personal medical data within the scope of the law. You have the right to know the information related to yourself at any time during the study.

7. How to get more information ?

In the course of the study, if you have any questions or do not understand anything related to this study, you can always ask the physician in charge of the study. Your doctor will leave you his / her phone number to answer your

questions. Tel : 15961727723

If there is any important new information in the course of the study that may affect the significance of your continued participation in the study, your doctor will notify you in time.

8. You can voluntarily choose to participate in the study or withdraw from the study. Whether to participate in the study depends entirely on your wishes. You can refuse to participate in this study, or withdraw from this study at any time during the study, which will not affect the relationship between you and the doctor, will not be discriminated against or retaliated against due to withdrawal, and will not affect your medical treatment and rights. In the best interest of you, if you require additional treatment, or if you do not comply with the study plan, or if an injury occurs in connection with the study or for any other reason, the research physician may terminate your participation in the study.

9. What to do now ?

Whether to participate in this study is up to you (and your family). Before you make the decision to participate in the study, please ask your doctor as much as possible until you fully understand the study. Thank you for reading the above material. If you decide to participate in this study, please tell your doctor that he / she will arrange everything for you. Please keep this information.

Informed consent signature page

I have read the introduction of the above research, and have the opportunity to discuss and ask questions about this research with doctors. All the questions I asked were answered satisfactorily. I know the risks and benefits of participating in this study. I know that participating in the study is voluntary, I confirm that there is sufficient time to consider this, and understand :

- 1 . I can always consult the doctor for more information.
- 2 . I can withdraw from this study at any time, without discrimination or retaliation, medical treatment and rights will not be affected.
- 3 . If I need to take other treatments due to changes in the condition, I will seek the doctor 's advice in advance, or tell the doctor truthfully afterwards.
- 4 . If I did not comply with the study plan, or had a study-related injury or any other reason, the research physician may terminate my participation in this study. I will get a signed and dated copy of the informed consent.

Finally, I decided to agree to participate in this study and to ensure that I follow the doctor 's advice.

Subject Name : _____ Signature : _____

Signature date : _____

A statement by researchers

I confirm that I have fully explained to the subjects the details of the study, including their interests and possible benefits and risks, and a signed copy of the informed consent.

Name of researcher : _____ signature of researcher : _____

Date : _____ Phone : _____

(Note : If the subject is illiterate, a witness signature is required, and if the subject is incapacitated, a legal representative signature is required)

Since the study was conducted in China, the informed consent was signed in Chinese and the document was translated into Chinese.