Study on HPV Vaccination Behavior and Comprehensive Intervention in Adolescent Female Adolescents Based on Biopsychosocial Medical Model: A Multi-center Randomized Controlled Trial

Informed Consent Form (Minor Version for ≥8-Year-Olds)

We invite you to participate in a clinical study titled: Study on HPV Vaccination Behavior and Comprehensive Intervention in Adolescent Female Adolescents Based on the Biopsychosocial Medical Model: A Multicenter Randomized Controlled Trial. This clinical study aims to investigate certain aspects. Below is an introduction to the study, and you may decide whether to participate after gaining a thorough understanding. If you have any questions or uncertainties regarding the following content, you may consult your study physician, who will provide detailed explanations until you achieve full comprehension.

1、 Why was this study conducted?

The HPV vaccine can help prevent diseases such as cervical cancer, but many girls like you have not yet received or completed vaccination. Through this study, we aim to identify factors influencing your and your family's decision to receive the HPV vaccine, and to evaluate whether a new communication and support approach can help more girls complete vaccination while improving communication and emotional well-being among you and your family.

2、 What is required prior to participating in the study?

If you agree to participate in this study, you must sign this consent form prior to the commencement of study activities. Your father/mother/guardian (hereinafter collectively referred to as "guardian") will sign another consent form. Participation in the study requires the consent of both you and your guardian. You may discuss and understand the information provided by physicians with your guardian. If you reach the age of majority during the study, you will be required to sign an informed consent form for adults. If any modifications to the informed consent form during the study result in a new version, you will also need to sign it again.

3、 How was this study conducted?

This study was conducted jointly at three hospitals (Children's Hospital Affiliated to Zhejiang University School of Medicine, Hong Kong Children's Hospital, and National University of Malaysia), with approximately 300 girls similar to your condition expected to participate. Our hospital plans to recruit around 200 participants.

If you agree to participate, the entire process will take approximately 6 months. You will be randomly assigned (similar to a lottery) to one of two groups:

Intervention group: In addition to routine vaccine education, you and your family will receive additional support, such as illustrated manuals, short videos, more detailed communication from physicians, and WeChat reminders.

Control group: Received routine vaccine introduction and services as currently provided by the hospital.

Regardless of which group you are assigned to, you will undergo follow-up visits at enrollment, 3 months, and 6 months. Follow-up methods may include in-person hospital visits or telephone/WeChat-based questionnaire completion. We will inquire about your knowledge regarding HPV vaccination, emotional state, and communication patterns with family members. Each session typically lasts approximately 15–20 minutes.

4、 What are the potential discomforts or risks associated with participating in this study?

The inherent risk of this study is minimal, with the primary risks arising from HPV vaccination itself. Potential adverse reactions may include injection site erythema, pain, or mild fever and headache. These reactions are typically transient, and physicians will provide guidance on management.

When completing the questionnaire, some questions may cause slight embarrassment or discomfort, and you may choose to leave them unanswered. Blood draw (if required) may result in transient pain or bruising.

If you experience any discomfort during the study, please inform your parents or the study physician promptly.

5、 What are the benefits of participating in this study?

You may become more familiar with the HPV vaccine, communicate more effectively with your family, and complete vaccination more smoothly. However, we cannot guarantee that you will necessarily experience these benefits. Your participation will assist physicians and researchers in providing better services for other girls and families in the future.

6、 Are there any other treatment options besides participating in this study?

This is not a disease treatment study, but rather a research investigation on health behaviors and communication support. You may opt out of participating in the study and still proceed with the standard HPV vaccination protocol.

7、 Is there a fee required to participate in this study?

The cost of HPV vaccination shall be borne by the patient according to the hospital's standard policy. No fees are charged for study-related questionnaires, follow-up visits, and certain examinations (e.g., psychological assessments).

8、 Will there be any compensation for participating in this study?

We will provide small transportation subsidies or souvenirs to families who complete all follow-up visits on time, as a thank you for your participation and time commitment.

9、 Do I have to participate in this study? Can I withdraw after participation?

Participation in this study is at your discretion. If you choose not to participate, no one will hold you accountable. If you disagree, neither your physician nor your parents can compel you to engage in the study.

If you agree now but later change your mind, you may discontinue participation in the study at any time. To withdraw from the study, simply inform your physician or your parents/legal guardians. Even if you do not wish to participate in this study, your physician will continue to provide care for you.

10、 During the study, under what circumstances will participants be asked to withdraw from the study?

If any of the following situations occur, the study physician has the authority to decide to discontinue your participation in the study:

- You did not follow the guidance of the project team, demonstrating poor compliance;
- The investigating physicians concluded that continued research would pose unnecessary risks.
- This study was halted by an ethics committee or a regulatory authority.

11、 If I participate in this study, will my privacy be protected?

All your research-related documents will be coded for identification, and any public reports on the study results will not disclose your personal information.

All data and associated codes are securely stored at the research institution (department) where the investigators are affiliated.

During the study period, we will promptly notify you and your parents/guardians of any significant new developments or medical information related to your health, such as recommendations for additional examinations to confirm these findings.

The information data generated from your participation in this study may be utilized for other approved scientific research purposes. You have the right to refuse secondary use of the information data, which will not affect any of your rights or interests, nor will it interfere with your continued participation in this study.

12、 Who should be contacted regarding questions about research or benefits?

You may ask questions regarding this study at any time and contact your physician by phone, who will respond to all your inquiries. If you experience study-related injuries or have any questions about the study, please contact:

Physician: Gao Huihui, Contact number: 15168281175

If you have any questions regarding your rights as a research participant, you may contact the ethics committee:

Name: Medical Ethics Committee of Children's Hospital Affiliated to Zhejiang University School of Medicine

Address: No.3333 Binsheng Road, Binjiang District, Hangzhou City, Zhejiang Province

Tel: 0571-86670076

Informed Consent Signature Page

I have read and understood the information contained in this informed consent form, have been given the opportunity to raise questions, and am satisfied with the responses to all inquiries. I voluntarily participate in this study.

I have been informed that I will receive a signed copy of this document.

Subject Name (Regular Script) _____

Subject's signature: _____

Signature date and time _____

Guardian's name (regular script) _____ Relationship with the subject _____

Guardian's signature: _

Signature: Date and Time _____ Contact Number _____

(This study requires a guardian's signature)

Statement of the informed consent form recipient:

I have explained all aspects of this study to the maximum extent possible within the comprehension of the subjects, answered all questions raised by the participants, and provided them with a signed copy of the informed consent form.

Name of informed consent recipient (regular script) _____

Informed consent recipient signature _____

Signature: Date and Time _____ Contact Number _____