Study on HPV Vaccination Behavior and Comprehensive Intervention in Adolescent Women Based on the Biopsychosocial Medical Model: A Multicenter Randomized Controlled Trial

Informed Consent Form (For Guardians)

Dear Parent or Legal Guardian:

Your child will be invited to participate in a study: A Study on HPV Vaccination Behavior and Comprehensive Intervention in Adolescent Women Based on the Biopsychosocial Medical Model: A Multicenter Randomized Controlled Trial. Your child's participation in this study is entirely voluntary. This informed consent form provides you with essential information about the study; please read it carefully before deciding whether to participate. If you have any questions or uncertainties, please consult the study physician, and the research team will address all your inquiries.

This research project, a clinical research initiative affiliated with the Children's Hospital of Zhejiang University School of Medicine, was led by Zhang Weifang and her team at the Children's Hospital of Zhejiang University School of Medicine, and jointly implemented with three medical institutions in Hong Kong, China and Malaysia. The study has been reviewed and approved by the Medical Ethics Committee of the Children's Hospital of Zhejiang University School of Medicine.

1. Why was this study conducted?

The HPV vaccine is an effective measure for preventing diseases such as cervical cancer; however, the vaccination rate among adolescent females in China remains low. Families often face challenges such as insufficient information, psychological concerns, or poor communication during vaccination decision-making processes. This study aims to explore various factors influencing HPV vaccination behavior among adolescent females and evaluate whether a comprehensive intervention program based on the "biopsychosocial" model—including health education, collaborative decision-support, psychological counseling, and family communication facilitation—can improve vaccination rates, enhance family decision-making experiences, and improve psychosocial outcomes.

2. What needs to be done before participating in the study?

If you and your child decide to participate in this study, we will require you to sign this informed consent form prior to initiating any study-related activities. If an updated version of the informed consent form is required during the study, you will need to sign it again.

3. How was this study conducted?

This study is an international, multicenter, randomized, open-label, parallel-controlled intervention clinical trial jointly conducted by three hospitals, with an estimated total enrollment of approximately 300 female adolescents aged 9 – 17 years and their guardians. Our institution plans to recruit approximately 200 participants.

The study is scheduled to commence in December 2025 and conclude in December 2028. Your child will require approximately 12 months from enrollment to the completion of the study.

Your child's participation in this study will entail the following:

(1) Randomization: After meeting the eligibility criteria and signing the informed consent form, your child will be randomly assigned in a 1:1 ratio to either the intervention group or the control group, with a 50% probability of being assigned to either group.

1) Intervention group: In addition to routine vaccination services, participants received comprehensive interventions based on the biopsychosocial model, including structured health education materials,

outpatient collaborative decision-making communication, WeChat message notifications, parent-child communication reminder cards, and telephone follow-ups for families with high decision-making hesitation.

2) Control group: Receives the current routine HPV vaccination education and services provided by each center, without additional implementation of the aforementioned comprehensive interventions.

(2) Follow-up Schedule: A total of three follow-up visits were conducted during the study period, at the enrollment time (baseline), 3 months, and 6 months. The follow-up methods included outpatient face-to-face visits, telephone calls, or WeChat questionnaires, each lasting approximately 15 – 20 minutes. The main contents included:

1) HPV vaccine knowledge questionnaire;

2) Psychological scales such as vaccine hesitancy, decision-making conflict, anxiety/depression;

3) Evaluation of parent-child communication quality;

4) Record vaccination status (first dose and complete vaccination course).

4. What are the potential discomforts or risks associated with participating in this study? Are there corresponding protective measures in place?

This study is a behavioral and psychosocial intervention study that does not alter the conventional types or procedures of HPV vaccination; therefore, the primary risks are identical to those associated with routine vaccination, including:

（1） Adverse reactions to vaccination: Symptoms such as redness, swelling, pain, fever, or headache at the injection site are typically mild and transient. Physicians will provide routine management and guidance.

（2） Psychological or emotional discomfort: The questionnaire or interview may involve topics related to health, psychology, or family communication, which in individual cases may cause temporary discomfort. You or your child may choose not to answer any questions you are unwilling to respond to, and the research team will maintain respect and support.

（3） Privacy Risk: All data will be deidentified and accessible only to the research team when necessary, with strict confidentiality maintained.

We will implement the following protective measures:

（1） Vaccination shall be administered by qualified healthcare professionals, and adverse reactions shall be managed according to standard protocols.

（2） The questionnaire was administered in a private setting, with questions designed to be neutral.

（3） Data is encrypted and stored, with strict access control.

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

Your child and family may gain the following benefits through this study: a more comprehensive understanding of HPV vaccine-related information; enhanced decision-making support and communication guidance; increased vaccination willingness or successful completion of vaccination; and improved parent-child communication quality and psychological well-being. However, we cannot guarantee that every participant will derive these benefits. Your participation will provide crucial scientific evidence for health promotion and collaborative family decision-making regarding adolescent HPV vaccination, benefiting more families in the future.

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

This study does not involve disease treatment but rather focuses on research into health behaviors and communication interventions. You may choose not to participate in the study and still administer the HPV vaccine to your child through conventional channels.

7. What should be done if a child is harmed as a result of participating in the study?

If your child sustains any injury related to vaccination or the study procedures during participation in the study, please contact the study physician immediately; we will provide prompt medical intervention. All injuries confirmed to be directly associated with the study will have their medical expenses covered by the study program, with corresponding compensation provided in accordance with applicable national regulations.

Even if you have signed this informed consent form, you retain all your statutory rights.

8. Is a fee required to participate in this study?

The cost of HPV vaccination shall be borne by the patient in accordance with the hospital's standard policy. Services related to questionnaire assessment, follow-up communication, and psychological support are provided free of charge.

9. Is there 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, in recognition of your and your child's time investment and cooperation.

10. Is participation in this study mandatory? Can I withdraw after participation?

No, participation in this study is voluntary. You may refuse to have your child participate.

You may also withdraw from the study at any time during the research process. Withdrawing from the study will not result in fines, discrimination, or retaliation, nor will it affect your child's future medical care or rights. If you wish for your child to withdraw from the study, please inform us. We will ensure that the child can complete the study in the safest manner possible.

11. During the study, under what circumstances will participants be required to withdraw from the study?

The investigating physician has the authority to discontinue your child's participation in the study under the following circumstances:

- You or your child have not followed the project team's instructions, demonstrating poor compliance.
- The investigating physicians concluded that continuing the study would pose unnecessary risks.
- This study was halted by the ethics committee or a regulatory authority.

12. What will happen when new information about this study becomes available?

During the study period, if any new information arises that may affect your child's continued participation in the study, the research physician will promptly inform you and your child, and provide you with sufficient consideration time to decide whether to continue participating in this study.

13. If my child participates in this study, is the information protected?

All research-related documents concerning your child will be distinguished by code. Any public reports on the results of this study will not disclose any personal information about you or your child.

All data and associated codes are securely stored at the institution (department) where the investigators are affiliated. The case materials of this study may be accessed by the investigators, the Medical Ethics Committee of Zhejiang University School of Medicine Affiliated Children's Hospital, and government regulatory authorities.

The information data generated from your child's 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 rights or interests of your child nor interfere with their continued participation in this study.

14. Who should you contact if you have questions about the research?

You may ask questions about any aspect you don't understand, and the project team will answer all your questions. If you feel the answers are incomplete or unclear, feel free to ask further questions until you are satisfied. Contact information is as follows:

Doctor: Gao Huihui, Contact Number: 15168281175

If you have any questions regarding your child's rights as a research participant, or wish to express any concerns or dissatisfaction during the study, you may contact the Ethics Committee:

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

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. I have raised all questions and am satisfied with the responses provided by the research physician. I have been given sufficient time and opportunity to inquire about the details of the study and to consider whether to participate in it.

I voluntarily consent to have my child participate in this study.

Signing this informed consent form does not constitute a waiver of any of my statutory rights.

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

I have authorized the relevant research personnel, the ethics committee, and government regulatory authorities to access my child's medical records.

I (Agree/Disagree) The data regarding my child in this study will be used for other research purposes.

Subject's Name (in standard Chinese characters) _____

Guardian's Name (in regular script) _____ Relationship with the Subject _____

Guardian's signature _____

Signature Date and Time: _____ Contact Phone Number: _____

(This study requires the signature of a guardian.)

Informed Consent Recipient's Statement:

I confirm that the details of this study, including the subjects 'rights as well as potential benefits and risks, have been explained to the subjects' guardians; all questions raised by the guardians have been answered; and a signed copy of the informed consent form has been provided.

Name of the person who obtained informed consent (in regular script): _____

Signature of the person obtaining informed consent _____

Signature Date and Time: _____

Contact Phone Number: _____

Impartial Witness Statement (where applicable):

I confirm that the investigating physician has accurately explained the contents of the informed consent form to the subject's guardian, conducted relevant discussions with the guardian, and provided the guardian with the opportunity to raise questions. The subject's guardian has voluntarily consented to their child's participation in this study.

Name of the impartial witness (in regular script): _____

Signature of the impartial witness _____

Signature Date and Time: _____

Contact Phone Number: _____

(If the subject or their guardian is illiterate, the signature of an impartial witness is required.)