Title: Multicenter Study on Symptom Cluster Heterogeneity and Related Gut Microbiota and Metabolite Mechanisms in Childhood Cancer Survivors

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Multicenter Study on Symptom Cluster Heterogeneity and Related Gut Microbiota and Metabolite Mechanisms in Childhood Cancer Survivors

Informed Consent Form (Guardian Version)

Dear Parent or Legal Guardian,

Your child is invited to participate in a research study titled 'Multicenter Study on Symptom Cluster Heterogeneity and Related Gut Microbiota and Metabolite Mechanisms in Childhood Cancer Survivors.' Participation is entirely voluntary. This informed consent form provides important information about the study. Please read it carefully before deciding whether to allow your child to participate. If you have any questions or concerns, please consult the research team, who will answer all your questions.

This study is conducted by Wang Jinhu and his team at the Children's Hospital affiliated with Zhejiang University School of Medicine. It has been reviewed and approved by the Medical Ethics Committee of the same institution.

1. Background and Purpose of the Study

In recent years, advances in medical technology have significantly improved survival rates in childhood cancer, with a 5-year survival rate reaching 71.9% in China. However, treatment-related side effects remain substantial. Many children continue to experience fatigue, pain, insomnia, depression, and other symptoms. These symptoms often co-occur and interact, forming 'symptom clusters' that significantly affect quality of life. Research suggests that these symptom clusters may be stable and driven by specific biological mechanisms. This study aims to investigate the characteristics and underlying mechanisms of symptom clusters in childhood cancer survivors. We will use questionnaires to assess symptom changes over time and collect fecal samples to analyze gut microbiota and metabolites, exploring their relationship with symptom clusters. This study will help improve understanding of health issues in childhood cancer survivors and provide scientific evidence for targeted symptom management strategies. Your child's participation will contribute to improving the quality of life of childhood cancer survivors.

2. What Needs to Be Done Before Participation?

If you and your child agree to participate, you will be required to sign this informed consent form before any study-related procedures begin. If updated versions of the consent form are issued during the study, you will be asked to sign the new version again.

3. What Will Happen If Your Child Participates?

This multicenter study will be conducted at three centers, including the Children's Hospital affiliated with Zhejiang University School of Medicine, Jiangxi Provincial Children's Hospital, and Fujian Provincial Children's Hospital. A total of 400 participants will be enrolled, with at least 200 recruited at this center.

Participation will last approximately 6 months. The study will follow routine clinical care and will not add extra visits, tests, or blood draws. After signing consent, researchers will assess eligibility (e.g., age, diagnosis, treatment completion time). If eligible, your child will be enrolled.

Study Procedures:

• Baseline Data Collection

We will collect basic information from medical records (age, sex, diagnosis, treatment, medical history). Additionally, questionnaires will assess demographic characteristics, symptoms, and quality of life. These standard clinical tools take about 30 minutes to complete.

• Longitudinal Follow-up

Over the next 6 months, follow-ups will occur every 3 months via phone, outpatient visits, or ward visits. Each follow-up includes the same questionnaire (~30 minutes).

• Fecal Sample Collection

If eligible, fecal samples will be collected during the study. The process is similar to normal bowel movements and does not cause significant discomfort. Clean containers will be provided along with instructions for proper collection and storage.

Clinical-related test results will be shared with the treating physician. Purely research data will not be individually reported. This study involves no treatment intervention.

4. Possible Risks and Discomforts

• Psychological Discomfort from Questionnaires

Answering questions about symptoms and psychological status may cause temporary emotional distress. Trained medical staff will provide support, and participation can be paused or stopped at any time.

• Risk of Privacy Breach

All data and samples will be anonymized using codes instead of names. Only authorized personnel can access the encrypted database. Personal information will not be disclosed or used outside research purposes.

• Future Use of Biological Samples

Fecal samples and data will only be used for this study. No genetic sequencing or commercial use is involved. Any future use will require additional written consent.

5. Potential Benefits

Your child will not directly benefit from participation, nor will individual results be reported. However, the study may contribute valuable data to improve symptom management and future interventions for childhood cancer survivors.

6. Alternative Options

This study does not affect your child's routine medical care. Standard treatments remain unchanged.

7. What Happens If Harm Occurs?

If your child experiences any adverse events during participation, please contact the research team immediately. Appropriate treatment will be provided.

If harm is causally related to the study, the research team will cover medical expenses and provide compensation according to applicable laws and regulations.

Signing this form does not waive any of your legal rights.

8. Is Participation Mandatory?

No. Participation is entirely voluntary. You may refuse or withdraw your child at any time without penalty or impact on future medical care.

Researchers may withdraw your child without consent if:

Study instructions are not followed;

Continued participation poses risk;

The study is terminated by sponsors, ethics committees, or regulatory authorities.

9. What If New Information Becomes Available?

If new information arises that may affect participation, you will be informed promptly and given time to decide whether to continue. After study completion, relevant results will be shared with you.

10. Costs

There are no additional costs for participation.

11. Compensation

Families completing all study procedures will receive a total compensation of 50 RMB, covering transportation and time costs. This compensation is unrelated to study outcomes and does not affect your right to withdraw.

12. Privacy Protection

All efforts will be made to protect your child's privacy within legal limits. No identifying information will appear in reports or publications.

Authorized personnel, ethics committees, or regulatory bodies may review study records.

Data will be coded and securely stored at the Children ' s Hospital affiliated with Zhejiang University School of Medicine for at least 10 years.

13. Contact Information

For questions, please contact:

Physician: Wang Jinhu

Phone: 13606636547

For questions about participant rights:

Ethics Committee: Medical Ethics Committee, Children's Hospital affiliated with Zhejiang University School of Medicine

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

Phone: 0571-86670076

Consent Signature Page

I have read and understood this informed consent form. I have had the opportunity to ask questions and am satisfied with the answers. I voluntarily agree for my child to participate. Signing this form does not waive any legal rights.

I will receive a signed copy of this document.

Participant Name:

Parent/Legal Guardian Signature:

Date/Time:

Phone:

Investigator Statement

I confirm that I have explained the study, including rights, risks, and benefits, to the guardian and provided a signed copy of this consent form.

Investigator Name:

Signature:

Date/Time:

Phone:

Consent for Illiterate Parents/Guardians

If the parent/legal guardian is illiterate, a study team member will read and explain this consent form and allow questions.

Impartial Witness Name:

Signature:

Date/Time:

Phone:

□ Not applicable

The impartial witness must be independent of the study and not influenced by the research team. They will participate in the consent process and ensure accurate communication of the study information.