THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

Cross-cultural adaptation and validation of the pediatric chemotherapy-induced neuropathy (P-CIN) for Chinese pediatric oncology patients: A multi-center study

Information sheet & **Consent form**

December 18, 2024

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

INFORMATION SHEET

CONSENT TO PARTICIPATE IN RESEARCH

Cross-cultural adaptation and validation of the pediatric chemotherapy-induced neuropathy (P-CIN) for Chinese pediatric oncology patients: A multi-center study

You are invited to participate in the above project chaired by Prof. Eva HO and conducted by Ms. MAO Ting, who is a post-graduate student at the School of Nursing in The Hong Kong Polytechnic University. The project has been approved by the PolyU Institutional Review Board (PolyU IRB) (Reference Number: HSEARS20250420003).

We aim to cross-culturally adapt and validate the original P-CIN for Chinese pediatric oncology patients.

In this study, you must be meet the following criteria: had been diagnosed with cancer; neurotoxic chemotherapies utilizing taxane-, platinum-, or vinca alkaloid due to the neurotoxicity is a severe and dose-limiting side effect of these chemotherapy drug; between the ages of 6-18; able to communicate, read, and write in Chinese without significant hearing and vision problems to ensure they understand our interview. Please do not participate in this study if you have the following conditions: plan to undergo radiotherapy; diagnosis of relapsed or second cancer; CNS tumors that have influence on CIPN symptoms; other developmental disorders (such as: Down's syndrome, other chromosomal disorders); other neuromuscular disorders (such as: traumatic brain injury, cerebral palsy); have other systemic diseases that cause toxicity in the peripheral nervous system; parents refused to give consent.

Before participating, you are typically provided with detailed information about the study, including its purpose, procedures, potential risks and benefits, confidentiality measures, and their rights as participants. You and your parents will be asked to provide informed consent, indicating the willingness to participate voluntarily. Then, you are invited to complete a questionnaire, which will take you about 15 minutes.

The testing should not result in any undue discomfort, inconveniences and without potential risks and side effects. During the process of the study, we will provide appropriate support or medical referrals if you feel any discomforts.

The information you provide as part of the project is the research data. Participants identifiers such as your names, addresses, and contact information will be replaced with unique codes to ensure that the archived samples and study records cannot be linked back to individual participants. We will minimize our use of personal data in the study as much as possible. Ms. MAO Ting and her supervisor Dr. Eva HO will have access to personal data and research data for the purposes of the study, other team members or collaborators will be forbidden to get the research data. Responsible members of The Hong Kong Polytechnic University may be given access for monitoring and/or audit

of the research. The information data will be stored in locked cabinets of Ms MAO Ting`s office for 2 years.

All information related to you will remain confidential. Archived samples and study records in paper documents will be stored in locked cabinets of my office and these documents will also be stored electronically, strong encryption password will be employed to protect the data from unauthorized access. The information collected will be kept until 2 years after project publication. The Hong Kong Polytechnic University takes reasonable precautions to prevent the loss, misappropriation, unauthorized access, or destruction of the information you provide.

Your participation is completely voluntary, and you have every right to withdraw from the study before or during the measurement without penalty of any kind. If you have any questions, you may ask our helpers now or later, even after the study has started.

You may contact Ms. MAO Ting (tel. no.: +85266754757/ email: 23040516R@connect.polyu.hk) of PolyU under the following situations:

a. if you have any other questions in relation to the study;
b. if, under very rare conditions, you become injured as a result of your participation in the study; or
c. if you want to get access to/or change your personal data before (the expiry date).

In the event you have any complaints about the conduct of this research study, you may contact Secretary, PolyU Institutional Review Board in writing (institutional.review.board@polyu.edu.hk) stating clearly the responsible person and department of this study as well as the Reference Number.

In case of a serious adverse event[1], please report to the Principal Investigator immediately and the Principal Investigator will be required to report it to the PolyU IRB within 48 hours upon the receipt of your report.

Thank you for your interest in participating in this study.

Prof. Eva HO
Principal Investigator/Chief Investigator

[1] SAE is any adverse event that:

- Results in death
- Is life threatening, or places the participant at immediate risk of death from the event as it occurred
- Requires or prolongs hospitalization
- Causes persistent or significant disability or incapacity
- Results in congenital anomalies or birth defects
- Is another condition which investigators judge to represent significant hazards

(Reference: NIA Adverse Event and Serious Adverse Event Guidelines. https://www.nia.nih.gov/sites/default/files/2018-09/nia-ae-and-sae-guidelines-2018.pdf)

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

Cross-cultural adaptation and validation of the pediatric chemotherapy-induced neuropathy (P-CIN) for Chinese pediatric oncology patients: A multi-center study

I _____ hereby consent to participate in the captioned research conducted by _____.

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e. my personal details will not be revealed.

The procedure as set out in the attached information sheet has been fully explained. I understand the benefit and risks involved. My participation in the project is voluntary.

I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without penalty of any kind.

Name of participant _____

Signature of participant _____

Name of Parent or Guardian _____

Signature of Parent or Guardian _____

Name of researcher _____

Signature of researcher _____

Date _____

Hung Hom Kowloon Hong Kong 香港 九龍 紅磡
Tel 電話 (852) 2766 5111 Fax 傳真 (852) 2784 3374
Email 電郵 polyu@polyu.edu.hk
Website 網址 www.polyu.edu.hk