PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM
(for adult subjects and interventional studies)

Title of study
Development and feasibility of e-Haematological Oncoloy Parents Education (eHOPE) for information support among parents of children with haematological cancer

Sub project 2
An open label randomised controlled feasibility trial of eHOPE on knowledge, caregiving self-efficacy and coping self-efficacy among parents of children with haematological cancer

Names of investigators and institutions
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Dr Teh Kok Hoi, Hospital Tunku Azizah
Dr Lee Chee Chan, Hospital Tunku Azizah

Name of sponsor
Assoc Prof Dr Tan Chai Eng

Introduction
You are invited to participate in this study because your child has been diagnosed with leukaemia or lymphoma. Parents of children with leukaemia or lymphoma need various types of information to support them to cope with stress. A website, eHOPE, has been developed specifically to support parents with information regarding your child's illness. This study aims to determine the feasibility of eHOPE to support parents by improving their knowledge and confidence in care for their child and coping with stress, through information support.
This document describes the details of the research trial. It is important that you understand why the research is being done and what it will involve. Please take your time to read through and consider this information carefully before you decide if you are willing to participate. Ask the study staff if anything is unclear or if you like more information. After you are properly satisfied that you understand this study, and that you wish to participate, you must sign the informed consent form. To participate in this study, you may be required to provide you doctor with some personal information and your child's health history. You will need to complete some questionnaires at the start and at the end of the study. You may be allocated to the intervention or control group. If you are allocated to the intervention group, you will be given access to eHOPE and will need to evaluate its effectiveness for this trial.
Your participation in this study is voluntary. You do not have to be in this study if you do not want to. You may also refuse to answer any questions you do not want to answer. If you volunteer to be in this study, you may withdraw from it at any time. If you withdraw, any data collected from you up to your withdrawal will still be used for the study. Your refusal to participate or withdrawal will not affect any medical or health benefits of which your child is otherwise entitled to.

This study has been approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia and Universiti Kebangsaan Malaysia (FF-2021-256).

What is the purpose of the study?

The purpose of this study is to determine the feasibility of information support through eHealth to parents of children with haematological cancer and to evaluate the preliminary effectiveness of eHOPE on knowledge and parents confidence.

This research is required because feasibility and effectiveness of information support through eHealth has yet to be proven via scientific methods.

This study will compare eHOPE with current practice of face-to-face information support by healthcare professionals.

A total of 64 subjects like you from Hospital Tunku Azizah and Hospital Pakar Kanak-kanak UKM (Hospital Tunku Ampuan Besar Tuanku Aishah Rohani) will be participating in this study. The study will start in August 2022 until October 2023. Your involvement is expected to be about 8 weeks.

What kind of study products will I receive?

If you agree to participate in the study, you will be randomly allocated into intervention or control group. You have equal chance of being assigned to each of the groups.

All participants will receive access to eHOPE on the Xperiencify platform and investigators will assist you to register for use of this website. eHOPE will contain information regarding the disease and care of your child. You will need to complete 4 activities in the website within 8 weeks. These activities are designed to maximise the benefits of eHOPE for you. You will still receive explanation regarding your child's care as usual from healthcare professionals. eHOPE will be used as an additional support for you.

Participants in the intervention group will receive access to all eHOPE contents immediately. For participants in the control group, access to eHOPE contents will be restricted for 8 weeks. You will receive explanation regarding your child's care as usual by healthcare professionals. You are also free to obtain information regarding your child's illness and care from other sources. After the study is completed, you will be given free access to eHOPE so that you can access the information within it.

What will happen if I decide to take part?

Participants from both groups will need to complete questionnaires at the beginning and at the 8th week of the study. Access restrictions to eHOPE contents will be automatically lifted for the control group after 8 weeks.

No tissue or blood samples are taken for this study. You do not need to come to the hospital for additional sessions apart from your child's scheduled appointments for treatment.

When will I receive the trial product and how should it be kept?
After signing the consent form, you will be assigned into either the intervention or control group. You will be registered to access eHOPE and login information will be sent to you via email. eHOPE can be accessed at your convenience from your computer or smartphone provided you have access to the internet.
You are not allowed to take screenshots of eHOPE contents to be shared to other parties throughout the study period. You are also not allowed to share your login details to other parties throughout the study period.

What are my responsibilities when taking part in this study?
You will need to complete the questionnaires for this study honestly. If you have any questions pertaining your child's health, you should discuss them with your child's treating doctors. Information in eHOPE website functions as supporting information and will not replace instructions from your child's doctor.

What kind of treatment will my child receive after my participation in the trial?
You will still be able to access eHOPE with your usual password. Your child's treatment will continue as usual.

What are the potential risks and side effects of being in this study?
There are no physical risks of participating in this study because no tissue or blood samples are required. If there are any queries regarding eHOPE, you may contact the researcher. If there are any queries regarding your child's care, you may discuss with your child's doctor.

What are the benefits of being in this study?
This study may or may not have any benefits for you. You will obtain special access to eHOPE website which is developed specifically for Malaysian parents. All information obtained from this study will help improve the current healthcare system to support parents of children with leukaemia or lymphoma.

What if I am injured during this study?
This study will not result in any injuries because it does not pose any physical risks to you.

What are my alternatives if I do not participate in this study?
You do not have to participate in this study to get treatment for your child's disease or condition. You are free to obtain supportive information from other websites or you're your child's healthcare provider.

Who is funding the research?
This study is self-funded by Assoc Prof Dr Tan Chai Eng, including research costs, eHOPE content development costs and Xperiencify fees. Your child's treatment cost will not be paid for by this study. You will be given an honorarium of RM50 to compensate your time and internet use at the end of the study.

Can the research or my participation be terminated early?
The study may be stopped or your participation may be terminated at any time. If the study is stopped early for any reason you will be informed. Your child's treatment will not be affected in any way.

Will my child's medical information and my personal information be kept private?
All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Individuals involved in this study and in your medical care, qualified monitors and auditors, the sponsor or its affiliates and governmental or regulatory authorities may inspect and copy your medical records, where appropriate and necessary
Data from the study may be archived for the purpose of analysis, but your identity will not be revealed at any time.
With your permission your child's doctor will be informed of your participation in the study.

Who should I call if I have questions?
If you have any questions about the study please contact the researcher, Assoc Prof Dr Tan Chai Eng at telephone number 012-3343145 or via email at ehopemalaysia@gmail.com.
If you have any questions about your rights as a participant in this study, please contact: The Secretary, Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-3362 8407 / 8205 / 8888.

INFORMED CONSENT FORM

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By signing below, I confirm the following:

I have been given oral and written information for the above study and have read and understood the information given.
I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.

I understand that my participation is voluntary, and I can at any time freely withdraw from the study without giving a reason and this will in no way affect my child's future treatment. I am not taking part in any other research study at this time. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the researcher's instructions related to my participation in the study.

I understand that study staff, qualified monitors and auditors, the sponsor or its affiliates, and governmental or regulatory authorities, have direct access to my medical record in order to make sure that the study is conducted correctly, and the data are recorded correctly. All personal details will be treated as **STRICTLY CONFIDENTIAL.**

I will receive a copy of this subject information/informed consent form signed and dated to bring home.

I agree/disagree* for my child's doctor to be informed of my participation in this study.
(*delete which is not applicable)

Subject:

Signature:	I/C number:
Name:	Date:

Investigator conducting informed consent:

Signature:	I/C number:
Name:	Date:

Impartial witness: (Required if subject is illiterate and contents of patient information sheet is orally communicated to subject)

Signature:	I/C number:
Name:	Date: