PARTICIPANT INFORMATION SHEET (PARENT/GUARDIAN)

Sydney Children's Hospital, Randwick

SUBSTUDY Workshop Focus Group

Project Title: A new digital and human-centred educational program to foster healthy behaviours and reduce cardiometabolic complications in children who survived cancer

Study Coordinator

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Before you decide whether your child will participate in this study or not, it is important for you and your child to understand why the research is being done and what it will involve. Please take the time to read the following information carefully.

1. Introduction

This is an invitation for **you and your child** in your care to take part in this research project because they are a survivor of childhood cancer and/or were previously invited to participate in an exercise study. This research project is a sub-study of the exercise study, 'a new digital and human-centred educational program to foster healthy behaviours and reduce cardiometabolic complications in children who survived cancer.' The aim of this sub-study is to invite survivors of childhood cancer and parents of survivors to focus groups to discuss their and your priorities of a digital health educational program, focused on improving physical activity levels.

This form tells you about the research project. It explains what is involved from you and your child, if you choose to participate. Knowing what is involved will help you decide if you or your child would want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your child's local doctor.

Participation in this research is voluntary. If you don't wish your child to take part, they don't have to. Your child will receive the best possible care whether or not they take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to you and your child taking part in the research project
- Consent for your child taking part in the focus group described
- Consent to use your child's personal and health information as described

You will be given a copy of this Participant Information and Consent Form to keep.

2. What is the purpose of this study?

Engaging in regular physical activity and cardiorespiratory fitness is important for survivors of childhood cancer to reduce their risk of chronic diseases including obesity, cardiovascular disease, and secondary cancers. We previously assessed the feasibility and acceptability of a digital educational intervention that was designed to educate childhood cancer survivors about health behaviours and engage them in physical activity with their family and friends.

The aim of this sub-study is to identify and discuss what your child's priorities and preferences are for a digital health educational program. We will include survivors who were previously invited to the pilot study and also other eligible survivors. These focus groups will give young survivors a voice and a key role in the co-design and co-development of our digital health program. We are also interested in identifying parent perspectives in the focus groups. We will use this information to improve our current version of the digital health program.

3. Why have you/your child been invited to participate in this study?

Your child is invited to participate in this study because:

- Your child was previously invited to participate in an exercise intervention OR
- Your child is aged between 8-13 years of age, and has completed cancer treatment for at least 12 months.

You are invited to participate in this study because:

- You are a parent/guardian of a child who is a cancer survivor.

4. What does participation in this study involve?

<u>For your child:</u>

Participation in this study for your child involves one 90-minute focus group facilitated by researchers of this study. Your child will be asked to complete a short questionnaire (before the focus group) consisting of a list of statements relating to a digital health program. They will be asked to rate each statement on a scale from least important to most important. All responses will be

anonymous. Researchers will collate the ratings of each statement. Discussions during the focus group will surround the top and bottom rated statements, and any other statements of interest. There will be a maximum of 8 children in each focus group. Participation for your child ends once the focus group has finished.

For you:

Participation in this study for you is also optional. If your child is interested in the focus groups but you do not wish to actively participate, you do not have to engage if you do not want to. You will however, be asked to supervise your child during the focus group discussion by assisting your child with technical support (if necessary). You do not have to be in the focus group with them. You will also be asked to complete a short questionnaire including components on your demographics and your child's clinical information such as their age, sex, cancer diagnosis, age at diagnosis and time since treatment completion.

If you are interested in participating in the focus group, you will be asked to join a focus group discussion with other parents of child survivors of cancer. You will also be asked to complete a short questionnaire consisting of the same list of statements that were provided to your child. You will be asked to rate each statement on a scale from what you think is least to most important to your child or other childhood cancer survivors. Researchers will collate the ratings of each statement before the focus group. There will be a maximum of 8 participants in each focus group. Participation for you will end once the focus group has finished.

5. About the focus group

The focus group will be semi-structured. Below is a general schedule:

Before the focus group	• Researchers will email participants an online anonymous questionnaire (Qualtrics) to complete. The questionnaire will include statements related to digital health programs, adapted from previous studies and modified to suit the aims of this study. Participants will be asked to rate each statement on a Likert scale, from least important to most important to them. • Researchers will obtain the results by exporting the data from the online survey software, Qualtrics. All data will be anonymous. • Researchers will collate the scores of each statement from all participants and rank them in order from most to least important. Higher scores of each statement indicate higher importance.
During the focus group (90-min)	• Welcome participants (10-min) • Explain purpose of sub-study (10-min) • Discussion about 3-5 top-rated statements made by participants (30-min) • Discussion about 3-5 bottom-rated statements made by participants (30-min) • Conclusion (10-min)
Time required in this sub-study:	Questionnaires (including ranking statements): 10-15min Focus group: 90 min

Study questionnaires:	• Demographic and clinical information • Rank statements on a Likert scale

6. How is this study being paid for?

There is no funding to support this sub-study.

7. Will you or your child benefit?

There is no direct benefit to you or your child. You and your child may personally benefit from this sub-study by having your voices and opinions heard. They may also benefit from being inspired to become or stay physically active to maximise their future quality of life and minimise the health problems that may face as adults.

8. Are there any risks?

There are minimal risks from participating in the focus groups. A potential risk is that participation in this study may ignite thoughts about one's health and the related emotions experienced may result in anxiety or distress.

If you or your child is experiencing distress, seek help from your local GP or treating oncologist. Crisis helplines are also available.
Lifeline 13 11 14
Kids Helpline 1800 55 1800

9. Do you or your child have to take part in this research project?

No. Participation in this study is voluntary. It is completely up to you whether you participate. Your decision will not affect your or your child's relationship with your child's treating team or staff at your hospital. If you wish to withdraw from the study at any point, you can do so without having to give a reason. If you wish to withdraw yourself and/or your child from the study, we will not collect any more information about you/them. We would like to keep the information we have already collected about you/your child to help us ensure that the results of the research project can be measured properly. Please let us know if you do not want us to do this.

10. Will taking part in this study cost me anything, and will I be paid?

Participation in this study will not cost you anything. You will not be paid for your participation.

11. What happens to the results?

We plan to share the results of the study with the ethics committee for ethical monitoring purposes. We will also present the results via publication in peer-reviewed medical journals and at medical conferences or other professional health services forum. When published, information will be provided in such a way that you or your child cannot be identified. Outcomes of this project can be provided to you if you wish. A tick box option is provided in the consent form if you wish to receive the study results after the study has concluded.

12. How will the focus groups be conducted? What information will be collected?

The focus groups will be conducted via online videoconferencing (Microsoft Teams) and will be recorded, with your consent. You will not need to download any software. Microsoft Teams enables

a transcription feature, that automatically transcribes the interview. The transcripts of the video conference will be downloaded electronically and reviewed for accuracy by researchers from this study. All electronic data collected will be stored securely in a password protected database on the UNSW Medicine network. If you are unavailable to attend the focus groups, a phone or online video-conference interview can be organised instead. The phone interview will also be audio-recorded, with your consent. If you prefer to do an interview, please discuss this with the study coordinator.

Any information collected and used in the study will be de-identified.

13. What will happen to the information I have provided?

Any information obtained in connection with this research project that can identify you or your child will remain confidential. Data collected will only be used for this specific project. It will only be disclosed with your permission, except as required by law. In any publication and/or presentation, information will be provided in such a way that your child cannot be identified, except with your permission.

Data collected in this study will be stored in locked cabinets and on password-protected network computer drives that can only be accessed by the study investigators. Your child's data will be coded so that it cannot be identified as belonging to them. All data collected will eventually be disposed of, after it has been stored for a minimum of 7 years after the final publication of results from this study.

14. What are the procedures in place to protect data integrity, confidentiality and prevent unauthorised access?

To maintain data integrity, access to any information is through a password-protected network which is consistently being backed up to prevent data loss.

To protect data confidentiality and prevent unauthorised access, all information about you and your child will be de-identified and stored on secure password-protected networks at the University of New South Wales. Only research staff directly involved with this study will have knowledge of and access to participant data. All information collected will remain confidential and disclosed only with your permission, or except as required by law.

15. Can I access research information kept about my child?

In accordance with relevant Australian privacy laws, you have the right to access the information collected and stored by the researchers about you. Please contact one of the researchers named if you would want to access your information. In accordance with regulatory guidelines, the information collected in this research project will be kept for at least 7 years. Access to information about you after this point will not be possible.

16. What should I do if I want to discuss this study further before I decide?

You can discuss this study with any member of your treating team, family or anyone you trust.

For further information, please contact the lead investigator, Ms Lauren Ha on lauren.ha@unsw.edu.au to discuss the study and answer any questions you have.

17. Who should I contact if I have concerns about the conduct of this study?

This research has been approved by the Sydney Children's Hospital Network Human Research Ethics Committee, Reference HREC/18/SCHN/471. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)* produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

If you have concerns about your rights as a participant in this research, or you have a complaint about the way the research is conducted, it can be discussed with the lead investigator (Ms Lauren Ha on 0433 788 662), or you can contact the SCHN Research Ethics Office on (02) 9845 1253.

Thank you for taking the time to consider this study.
If you wish to take part, please return the signed consent form. The lead investigator will then confirm your participation and answer any questions you may have.