PARTICIPANT INFORMATION SHEET (ADULT)

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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Investigators

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Before you decide whether you will participate in this study or not, it is important for you a 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 you to take part in this research project because you are a health professional or stakeholder interested in physical activity for childhood cancer survivors. 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.

Participation in this research is voluntary.

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 taking part in the research project

- Consent to taking part in the focus group 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 survivors', parents of survivors', health professionals' and stakeholders' priorities and preferences for a digital health educational program. These focus groups will give young survivors a voice and a key role in the co-design and development of our digital health program.

Additionally, we are holding a second focus group to explore priorities from health professionals, and stakeholders for a digital health program for childhood cancer survivors. We will use this information to improve our current version of the digital health program.

3. What does participation in this study involve?

Participation in this study involves partaking in a focus group discussion with other parents of survivors, health professionals and stakeholder. You will also be asked to complete a short online questionnaire consisting of demographic components about yourself. A list of statements relating to digital health and physical activity will also be provided to you to rate on a scale from what you think is least to most important for childhood cancer survivors. All responses will be anonymous.

Researchers will collate the ratings of each statement before the focus group. Discussions during the focus group with health professionals such as nurses, oncologists and exercise physiologists, and stakeholders will surround the top and bottom rated statements, and any other statements of interest. There will be a maximum of 8 participants in each focus group. Participation for you will end once the focus group has finished.

4. 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:	Questionnaire (including ranking statements): 10-15min Focus group: 90-min
Study questionnaires:	• Demographic information • Rank statements on a Likert scale

5. How is this study being paid for?

There is no funding to support this sub-study.

6. Do you have to take part in this research project?

No. Participation in this study is voluntary. It is completely up to you whether you participate. If you wish to withdraw from the study at any point, you can do so without having to give a reason. We would like to keep the information we have already collected about you 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.

7. 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.

8. 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.

9. 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.

10.

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

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

Any information obtained in connection with this research project that can identify you 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 you 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. 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.

12. 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 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.

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

You can discuss this study with 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.

14. 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.