



The Sydney  
children's  
Hospitals Network

### Parent / Guardian Information Sheet

<b>Study Title</b>	A digital health education program promoting physical activity for childhood cancer survivors: A hybrid effectiveness-implementation trial of 'Making Moves'
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## 1. Introduction

This is an invitation for your child to take part in a research study titled, 'A digital health education program promoting physical activity for childhood cancer survivors: A hybrid effectiveness-implementation trial of 'Making Moves''. This study will be conducted in UNSW Sydney in conjunction with the Kids Cancer Centre.

This information sheet tells you about the study. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want your child to take part in the study. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about.

Participation in this research is **voluntary**. If you do not wish for your child to take part, they do not have to.

## 2. What is the purpose of this study?

Many childhood cancer survivors are at increased risk of developing late effects, such as obesity and heart disease. Having low physical activity levels, low fitness levels and high sedentary levels (sitting time), can further increase the risk of obesity and heart disease. Many childhood cancer survivors do not meet the recommended physical activity guidelines and have low fitness levels. It is important

for young survivors to engage in a healthy and active lifestyle so that their behaviours will continue into adulthood.

This research project has two main aims:

- i. To test how effective our online physical activity program, called 'Making Moves' is on improving young survivors' physical activity self-efficacy (meaning their confidence in their ability to be physically active), and
- ii. To explore the barriers and facilitators of implementing the Making Moves program within healthcare and community settings. We want to understand whether the *Making Moves* program can be implemented and scaled up in the real world

*Making Moves* is an online health education program teaches young survivors about the importance of having a healthy and active lifestyle. Survivors will also have access to free online exercise consultations with an Accredited Exercise Physiologist.

This study is funded by The Kids' Cancer Project. Participation in this study will not cost you anything. You will not be paid for your participation.

### **3. Why has my child been invited to this study?**

Your child is invited to participate in this study because:

- Your child was diagnosed with cancer as a child prior to age 18 years.
- Your child is currently 8-21 years of age.
- Your child has completed active cancer treatment at least 6 months ago OR is on maintenance therapy.

To be eligible for the study, your child must have clearance to exercise signed by your GP or oncologist.

### **4. Does my child have to take part in this study?**

Participation in any research project is voluntary. If you do not wish for your child to take part, they do not have to. If you decide that they can take part and later change your mind, you are free to withdraw your child from the project at any stage.

Your decision that your child can or cannot take part, or that they can take part and then be withdrawn, will not affect their routine care or relationship with professional staff.

If you decide you want to take part in the research project, you will be asked to sign the consent section.

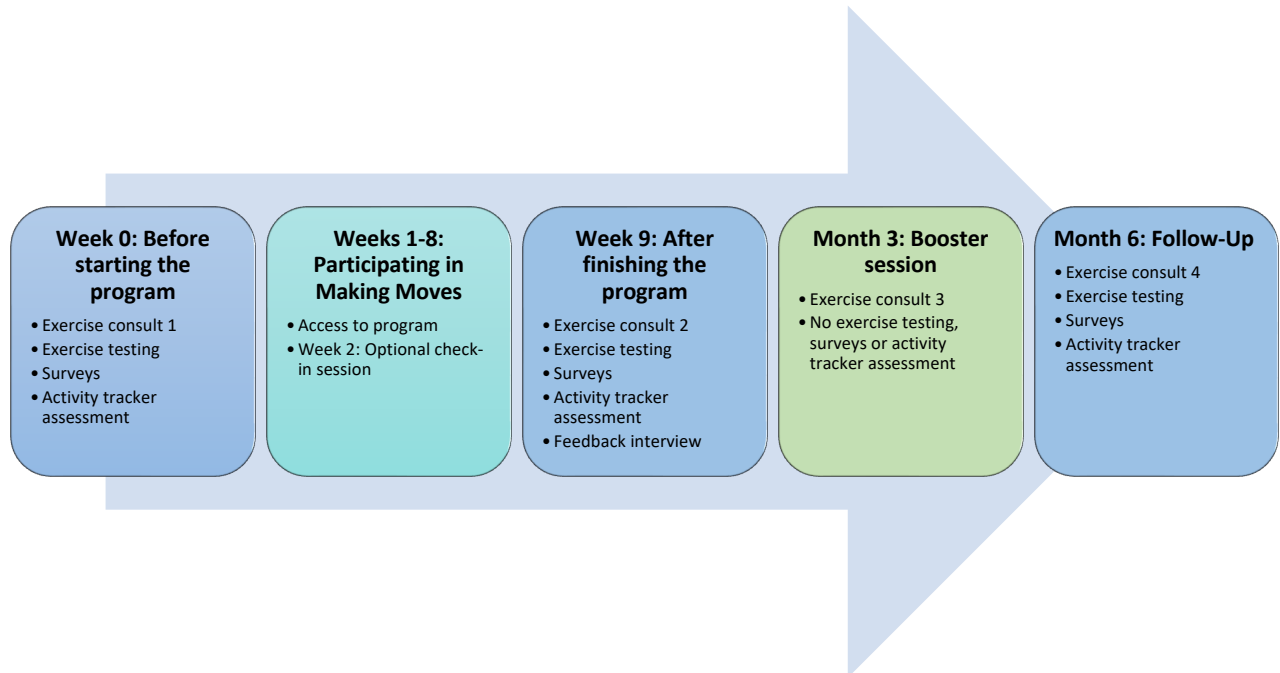
By signing it you are telling us that you:

- 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 intervention and tests described.
- Consent to use your child's personal and health information as described.

You will be given a copy of this document to keep.

## 5. What does participation in this study involve?

If you decide that your child may take part in this study, they will complete an 8-week health education program about physical activity. This study involves an **online program** called *Making Moves* that was co-designed with childhood cancer survivors, parents, health professionals and researchers. The program includes 8 education modules with health behaviour information and physical activity videos to guide your child to increase their physical activity levels at home. You and your child will also have access to **five online exercise consultations** with an Accredited Exercise Physiologist for exercise guidance, education, and goal setting. Your child will receive a **free fitness tracker (Fitbit)** to help them monitor their physical activity.



**Figure 1. Timeline and summary of the study.**

Below outlines more information of what the study involves at each time point.

### ***Before the intervention (week 0) – First exercise consultation (approx. 60 min)***

After your child opts into the study, they will be asked to complete a survey and wear a research activity monitor for 5 days. Then your child will have their first exercise consultation with an Accredited Exercise Physiologist and they will be introduced to the Making Moves program. You and your child will be given the opportunity to ask questions. The exercise physiologist will also supervise and guide your child on two fitness tests, a walking test and a short strength test. The exercise physiologist will discuss with your child about their physical activity levels, any barriers to being physically active, and create some goals.

### ***During the intervention (weeks 1-8)***

Your child will gain access to our program which involves a mobile friendly website and fitness tracker (Fitbit). They will need a tablet, mobile or computer to access the program. The program website consists of weekly educational modules and physical activities designed to involve parents/carers and friends. We will encourage your child to wear the fitness tracker daily to help monitor their activity.

### ***Check-in session (weeks 2-3) – Optional session (approx. 30 min)***

Your child will be invited to complete an optional “check in session”. This session will allow the exercise physiologist to assess your child’s engagement in the program and can assist in troubleshooting any issues. It will also be another opportunity for the exercise physiologist to provide further exercise support, offer advice or education, and answer any questions. There will be no exercise testing conducted.

***After the intervention (week 9) – Exercise consultation + Program feedback (approx. 60-90 min)***

After your child has completed the program, they will attend their second online consultation with the exercise physiologist. The consultation will be similar to the first. Your child will complete a survey, complete the two fitness tests (walking test and strength test), have a discussion about their physical activity, review their previous goals and create new goals.

Before the online consultation, your child will wear the research activity monitor for 5 consecutive days (including two weekend days). Following the exercise consultation, the exercise physiologist will interview you and your child about different aspects of the program including its potential for implementation.

***Booster session (3 months after completion of program; approx. 30 min)***

Your child will be invited to complete a “booster session” online for further physical activity support. This booster session will allow the exercise physiologist to assess your child’s current physical activity levels, review goals, and identify their barriers and facilitators to exercise. The exercise physiologist will offer advice, recommendations, and tailored exercise support. Your child will also be required to report their recent physical activity. There will be no exercise testing conducted.

***Follow-Up (6 months after completion of program; approx. 60min)***

Your child will attend their last online consultation with the exercise physiologist. This last consultation will be similar to the first consult. Your child will complete a survey and complete the two fitness tests. The exercise physiologist will assess your child’s current physical activity levels, review and set new goals, and discuss any barriers and facilitators to exercise that they may be experiencing. The exercise physiologist will also provide recommendations to assist the participant in achieving a physically active lifestyle in the short- and long-term. Before the online consultation, your child will wear the research activity monitor for 5 consecutive days (including two weekend days).

***Study assessments:***

1. Questionnaire

Your child will be asked to complete a questionnaire pack. The questionnaire includes components on:

- Physical activity levels
- Physical activity self-efficacy
- Physical activity enjoyment
- Health-related quality of life
- Acceptability questionnaire (only completed after the intervention)
- Mental wellbeing

If your child needs assistance with the questions, you may help them. The questionnaire can be sent in the mail upon request or by e-mail.

## 2. Physical activity levels (using a research activity monitor)

Your child will be asked to wear a research activity monitor for 5 consecutive days (including two weekend days). After they have finished wearing the activity monitor, you will be provided with a paid envelope to return it back to researchers. All data collected on the activity tracker will be anonymous. This data will be downloaded by the research staff named on this study. We will use this data to assess your child's physical activity levels based on intensity (light, moderate and vigorous) to help us understand the impact of the program on your child's physical activity levels. Once the data has been transferred onto our study folder on the secure UNSW network drive, the activity monitors will be reset and all data on the devices will be deleted.

## 3. Fitness tests:

Your child will perform two fitness tests, supervised online by the exercise physiologist during the first, second and fourth consultations. We also ask you to assist in-person. They will complete:

- Walking test (6-minute walk test)
- Lower body strength test (sit-to-stand test)

## 6. What does the Making Moves program involve?

Below is a summary of the *Making Moves* program:

<b>Making Moves Website</b>	<ol style="list-style-type: none"><li>1. Modules that teach your child about physical activity and healthy eating</li><li>2. Health information, fun facts, physical activity tips</li><li>3. Physical activity videos</li></ol>
<b>Number of modules:</b>	8
<b>Time required to take each module:</b>	10-20 minutes Videos range from 1-20 minutes

The *Making Moves* module topics are:

Module number	Topic
1	Welcome
2	Living a physically active lifestyle
3	Sedentary behaviour: don't just sit and sit and sit!
4	How much exercise do I need to do?
5	Staying fit and motivated
6	Let's get stronger!
7	Flexibility, balance, and coordination
8	Healthy eating

Examples of home-based physical activity videos are:

- Bodyweight strength exercises (e.g., wall sit challenge, explanations on how to do a squat or push-up).
- Balance exercises (e.g. explanations on how to balance, standing on one leg)
- Flexibility (e.g., stretching exercises, yoga)
- Fitness and skills (e.g., basketball, soccer)

All modules are divided into three age groups (i.e., 8-12 years, 13-17 years, and 18-21 years) to ensure the education and physical activities are age-appropriate and relevant to your child.

### **7. Can my child keep the fitness tracker after the study?**

Your child can keep the fitness tracker (Fitbit) as a reimbursement for their time participating in the study. This will allow them to continue monitoring their own physical activity levels beyond the study. To join this study, they can use the device independently. They do not need to download the corresponding app, but they can if they wish to.

They cannot keep the research activity monitor (GeneActiv Accelerometer). You will need to return the research activity monitor by mail after your child has worn it for 5 consecutive days.

### **8. What are the possible risks and disadvantages of taking part?**

There are minimal risks with participating in the two exercise tests (walking test and strength test), but these risks are similar to participating in regular exercise. To ensure your child is safe, the exercise physiologist will screen them prior to the tests and will remotely supervise them during the test. They will also require a parent or responsible adult to assist with the test procedures.

To participate in this study, your child will need a referral letter from their general practitioner (GP) or oncologist for clearance to exercise unsupervised.

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 available.

Lifeline 13 11 14

Kids Helpline 1800 55 1800

### **9. What are the possible benefits of taking part?**

Your child may personally benefit in several ways from this study including learning new physical activity skills, building confidence to manage their physical activity levels and improving their health behaviours. Your child will also receive a free activity tracker to assist in their daily physical activity monitoring and receive professional guidance and tailored support from an Accredited Exercise Physiologist. However, it may not be guaranteed that your child will benefit from participation in this study.

### **10. What information is collected about my child from the online platforms?**

#### ***Making Moves platform (Wix)***

The Making Moves digital platform is powered by Wix, a professional website software company. We will create an anonymous user account for your child so that Wix do not collect any personal information about them. After the study finishes, we will delete all user accounts.

Wix have implemented security measures designed to protect the information that has been shared on the website. Wix will collect information including:

- Information we provide to Wix: We do not provide any information to Wix.
- Information Wix collect when users use the services: Wix may collect Personal Information, such as Visitors' and Users' browsing and 'click-stream' activity on the Services, session heatmaps and scrolls, non-identifying Personal Information regarding the Visitor's or User's device, operating system, internet browser, screen resolution, language and keyboard settings, internet service provider, referring/exit pages, date/time stamps, etc. Wix will also collect website analytic information including the number of site sessions visited by each user, session and site duration, site pages accessed, and type of device used to access the site.
- Information Wix collect from other sources: Wix may receive Personal Information about participants from third-party sources, such as i) security providers, fraud detection and prevention providers for example to help Wix screen out users associated with fraud; ii) advertising and marketing partners in order to monitor, manage and measure their ad campaigns.

Please refer to the Wix privacy policy for more information: <https://www.wix.com/about/privacy>

### **Fitbit**

We do not provide any information to Fitbit, nor will we receive any sensitive information from/via Fitbit. For this study, you/your child do not need to download the corresponding app (but you can if you like). The Fitbit device can be used independently.

When using the Fitbit device and corresponding app, Fitbit will collect your information including account information when setting up the device (name, email address, password, date of birth, gender, height, weight and in some cases, phone number) and additional information if you enable certain features such as logs for food or sleep.

Fitbit do not sell personal information. Fitbit do not share any personal information except:

- When users agree or direct Fitbit to share (such as when using community features like forums).
- For external processing (such as customer support, information technology, data analysis, research)
- For legal reasons or to prevent harm
- For joint processing of profile information (if users choose to move their accounts to Google).

You can refer to the Fitbit privacy policy for more information:

<https://www.fitbit.com/global/au/legal/privacy-policy>

## **11. What will happen to the information about my child?**

By signing the consent form you consent to the research team collecting and using personal information about your child for the research project. Your child's privacy and confidentiality will be protected at all times. Their information will only be used for the purpose of this research study and it will only be disclosed with your permission, except as required by law. For example, researchers are required to report if a participant is believed to be at risk of harm.

In order to protect your child's privacy, the study team will remove any information that may be used to identify them from any study documents, and instead of their name appearing on the documents, they will be identified by a specific study code number that applies only to them. Only this code number will be used on any research-related information collected about your child for this study, so that their identity as part of the study will be kept completely private. Only the study team at UNSW Sydney/Kids Cancer Centre will have the ability to link this code number with your child's personal information, and the linking information will be kept in the secure UNSW network drive. Your child's data will be stored for 15 of years after the study finishes.

If you withdraw your child from the study, we will not collect any more information about them. We would like to keep the information we have already collected about 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.

## **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 and your child will be anonymous and stored on secure password-protected networks at UNSW Sydney. Any paper copies of research information will be digitized immediately and uploaded to the same study folder on the UNSW network drive. Any paper copies will then be shredded and disposed of. Only research staff directly involved with this study will have knowledge of and access to participant data. All information collected (including data from the questionnaires, exercise consults, research activity tracker and online website), will remain confidential and disclosed only with your permission, or except as required by law.

## **13. How will the results of the study be distributed?**

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that your child cannot be identified, except with your explicit permission.

You can indicate on the consent form if you wish to receive a lay summary of the study findings.

## **14. Who should I contact if I have any questions?**

If you have any questions or want more information about this study before or during participation, you can contact our study team on [makingmoves@unsw.edu.au](mailto:makingmoves@unsw.edu.au).

## **15. Who do I contact if I have concerns about the study?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This study has been approved by the Sydney Children's Hospitals Network (SCHN) HREC (**approval number: 2023/ETH01614**).



If you have any concerns or complaints about any aspect of the project or the way it is being conducted, you may contact the Executive Officer of the SCHN HREC on (02) 9845 1253 or [SCHN-Ethics@health.nsw.gov.au](mailto:SCHN-Ethics@health.nsw.gov.au).

*This Information Sheet is for you to keep. We will also give you a copy of the signed consent form.*