Information statement and consent form

HREC Project Number: 37100

Research Project Title: Concussion Essentials

Principal Researcher: Prof Vicki Anderson, Theme Director, Clinical Sciences, Murdoch Children’s Research Institute

Version Number: 8 Version Date: 23/09/2020

Thank you for taking the time to read this Participant Information Statement and Consent Form. We would like to invite you to participate in a research project that is explained below.

This document is 8 pages long. Please make sure you have all the pages.

What is an Information Statement?
These pages tell you about the research project. It explains to you clearly and openly all the steps and procedures of the project. The information is to help you to decide whether or not you would like to take part in the research. Please read this Information Statement carefully.

Before you decide to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

Important things you need to know

- It is your choice whether or not you take part in the research. You do not have to agree if you do not want to
- If you decide you do not want to take part, it will not affect the treatment and care you get at The Royal Children’s Hospital or in the community.

If you would like to take part in the research project, please sign the consent form at the end of this Information Statement. By signing the consent form you are telling us that you:

- understand what you have read
- had a chance to ask questions and received satisfactory answers
- consent to taking part in the project.

We will give you a copy of this information and consent form to keep.
1. **What is the research project about?**

In general, most children with a concussion recover within 4 weeks after their injury. Some children, however, continue to have ongoing symptoms such as headaches, dizziness, fatigue, memory or concentration problems, depression and anxiety beyond this period. These symptoms may limit their ability to return to school, sport and social activities.

We know from past research that children who have ongoing symptoms may benefit from clinical assistance (e.g., physiotherapy) and education about their symptoms. It can be difficult for families to identify the best treatment or source of information/education in their community.

This project brings together a range of health professionals, including medical doctors, physiotherapists, and psychologists, who are specialists in concussion management and education. The aim of the study is to compare two different treatments for children who have had a concussion: an individualised program and standard care.

We hope up to 216 families will take part in this project.

2. **Who is funding this research project?**

This study is funded by The Royal Children’s Hospital Foundation and the MACH MRFF RART 2.2.

3. **Why am I being asked to take part?**

We are asking you to take part because you are aged between 8-18 years, had a concussion in the past 2-3 weeks and have ongoing symptoms.

4. **What do I need to do in this research project?**

Participation in this research will last for 3 months. You will be put in to one of two groups:

- **Concussion Essentials program:** Complete an individualised treatment program
- **Usual Care program:** Receive standard care from The Royal Children’s Hospital or community

This will be done by chance, similar to tossing a coin, so you have an equal chance of being in either group. This will help us to compare which program works best. Neither you, your parent/guardian, or your doctor can choose which group you are put in.

Both groups involve participation once per week until symptoms have improved, for up to 8 weeks. The Concussion Essentials treatment program will take approximately 1 hour, and the Usual Care program will take approximately 15 to 30 minutes each week.

Baseline and post-program assessments will occur at 2-3 weeks and 3 months post-injury for both groups. Part of these assessments will occur online and part will be in-person. The in-person visits will take place at locations in Mount Waverley, St Kilda, or North Melbourne.

If you are in the Usual Care group, you will have the option to complete the Concussion Essentials treatment program if you are still experiencing symptoms after the post-program assessment.
The details below describe what is involved at each visit and when they occur.

<table>
<thead>
<tr>
<th>Procedures</th>
<th>Screening</th>
<th>Baseline Visit</th>
<th>Program</th>
<th>Post-Program Visit</th>
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<tbody>
<tr>
<td></td>
<td>Up to 10 days after concussion</td>
<td>10 days after concussion</td>
<td>2-3 weeks after concussion</td>
<td>Week 1</td>
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<tr>
<td>Screening questions to see whether you are able to participate</td>
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<td>CE program</td>
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<td>Usual Care program</td>
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<td>Symptom assessment</td>
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<td>Sleep, fatigue, physical activity and pain questions</td>
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<td>Physical assessment</td>
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<td>Cognitive assessment</td>
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<td>Emotional health questions</td>
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<td>Return to normal activity questions</td>
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<td>Quality of life questions</td>
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<td>Cost of concussion questions</td>
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<tr>
<td>Optional DHS consent</td>
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*On-site and home program available for up to 8 weeks

**Concussion Essentials Program:** If you are put in to the Concussion Essentials program, you will complete an individualised program, provided by trained clinicians. Depending on your symptoms, you will receive treatment delivered by a physiotherapist and/or treatment delivered by a psychologist. This program will be delivered primarily online. Some physiotherapy treatment may need to be delivered in-person. Your physiotherapist will let you know if this is required. You and your parent/guardian will receive education and advice about physical activity, fatigue, sleep, and lifestyle. You and your parent/guardian may also receive education and advice about managing school and how to manage headaches. Audio or video may be taken of you so the research team can see how well the therapists are able to deliver the program.

**Usual Care Program:** If you are put into the Usual Care program, your child will receive standard care from The Royal Children’s Hospital or community and weekly symptom assessment via an online survey. You will also receive a summary report of your child’s baseline assessment.

**Symptom assessment:** We will ask you and your parent/guardian about certain symptoms before your injury, and about these symptoms currently via a questionnaire.
Questionnaires: We will ask you and your parent/guardian to answer questions about the following things:

- Sleep habits
- Physical activity
- Pain
- Emotional health
  - Some of the information you’ll be asked will be about your mood. If we have concerns about your safety, we have permission to discuss this with your parent and/or GP.
  
  [Signature required]

- Return to normal activity
- Quality of life
- Additional medical care and costs

Physical assessment: In the physical assessment, you will see a physiotherapist. You will complete tasks such as walking or jogging on a treadmill, balance tests, and tests of your eye and neck movement.

Cognitive assessment: In the cognitive assessment, your child will be asked to complete tasks which assess their cognitive function, such as puzzles or memory tests.

To assist with determining the range and cost of services accessed, including presentation to other hospitals, we will also link your demographic and clinical information with the Victorian Department of Health and Human Services.

Access to medical records and administrative information: If you were treated or admitted to The Royal Children’s Hospital for the concussion, we will access your medical record to collect information such as date of birth, sex, home address and phone number. We will also collect information about your injury including how it occurred, any symptoms and where the injury is located, and the results of any tests e.g., CT or MRI scans. As well as, administrative information such as admission and discharge dates, and hospital cost. This information will be used for research purposes.

If you presented to a clinical service other than The Royal Children’s Hospital we will ask your parent/guardian to provide a copy of the letter from the service with details of your injury. If your parent/guardian does not have a letter we will ask for their permission to contact the clinical service for this information.

Optional Consent
Contact about future research
We would like you to consider letting us send you information about new research projects that may be suitable for you. The information we send will give you the full details about the project. It is your choice whether you agree to take part in any future project or not. You are not obliged to take part in any future research you are sent information about.

Use of data in future research
We would like you to consider giving us permission to store information (not including Medicare or PBS data) from this research project for use in future ethically approved research. The information collected from you during this study will only be used for an extension of the present study or in a related research project that is conducted at or closely affiliated with the Murdoch Children’s Research Institute. Any future study will be approved by the relevant ethical committee and your privacy and confidentiality will be maintained at all times. Participation in a future research project is voluntary. You do not have to take part in any future project if you do not want to.

All electronic data and databases will be stored on a secure MCRI server. All paper forms will be stored securely in the Clinical Sciences offices at the Murdoch Children’s Research Institute. The information shared with future research projects will be re-identifiable. This means that we will remove your name and give the information a special code number. Only the research team can match your name to the code number, if it is necessary to do so.
As the participants in this project are under 18 years old, information will be kept until the youngest participant turns 25 years old. The research information may be destroyed or kept indefinitely in secure storage after this time. If you turn 18 and have not previously given consent for your data to be used in any future studies we contact you and ask if you would like to opt out of the research studies and have your data destroyed. If you do not opt out your data may be used in future research.

Collection of data from Department of Human Services (Medicare and PBS)
We would like your permission to let us link to information collected by the Department of Human Services (DHS). The information we collect from the Department of Human Services will help us to estimate the costs associated with child concussion, in order to do this, we will ask you, or your parents, to complete a Department of Human Services consent form. Where a child is on two Medicare cards, both cardholders will be required to sign the consent form, otherwise only claims histories from the cardholder who has signed the consent form will be supplied.

If you are 14 year or older, you will be asked to fill out a consent form authorising the study access to your complete Medicare and Pharmaceutical Benefits Scheme (PBS) data, as outlined on the back of the consent form. If you are under 14 years and on two Medicare cards, both card numbers and cardholder signatures will be required. Medicare collects information on your doctor visits and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. The consent form is sent securely to the Department of Human Services who holds this information confidentially.

5. Can I withdraw from the project?
If you give your consent and change your mind, you can withdraw from the project. You do not need to tell us the reason why you want to stop being in the project. If you leave the project we will use any information already collected unless you tell us not to. If you do not want us to continue using information already collected from you, please contact Nicholas Anderson by phone or email (details on page 6) to inform him of your wishes.

6. What are the possible benefits for me and other people in the future?
We cannot promise that you will get any benefits from this project, however our previous research suggests possible benefits which may include improvement in some of the ongoing symptoms that your child may experience after the concussion. Parents who completed our pilot study have stated that the sessions were informative and valuable, that they felt supported during their child’s recovery and that their children felt at ease during and after completing the sessions.

We expect the main benefits of this study to be for others in the future. We hope the information we get will show us the best way to manage concussion, and allow us to help other clinicians in the community to treat children with concussion.

7. What are the possible risks, side-effects, discomforts and/or inconveniences?
If you become upset or unhappy due to taking part in this project, we can arrange for counselling or other suitable support. Any counselling or support will be provided by someone who is not part of the research team. You can delay or end your participation in the project if you feel any distress.

During the study, you and your parent/guardian will be asked questions about your emotional health and anxiety. If you or your parent/guardian are experiencing severe distress, you or your parent will receive support from the clinical research team, if needed we will give you a referral for appropriate support. You will
be asked to take part in physical assessments. If you experience physical discomfort beyond what is expected in the study, we will give you a referral for appropriate support.

The inconveniences of the study include the time to attend in-person study assessments.

8. What will be done to make sure my information is confidential?

In this study we will collect and use personal and health information about you for research purposes. Any information we collect that can identify you will be treated as confidential. It will be used only in this project, unless otherwise specified. We can disclose the information only with your permission, except as required by law.

All information will be stored securely in the Clinical Sciences offices at the Murdoch Children’s Research Institute.

The following people may access information collected as part of this research project:

- The research team involved with this project
- The Royal Children’s Hospital Human Research Ethics Committee

The stored information will be re-identifiable. This means that we will remove identifying information such as your name and give the information a special code number. Only the research team can match your name to the code number, if it is necessary to do so.

As the participants in this project are under 18 years old, information will be kept until the youngest participant turns 25 years old. The research information may be destroyed or kept indefinitely in secure storage after this time. All MBS and PBS data will be deleted after 7 years from publication or 10 years from the date it was supplied (whichever is sooner).

9. Will I be informed of the results when the research project is finished?

We will send you a summary of the overall project results. The summary will be of the whole group of research study participants, not your individual results.

10. Who should I contact for more information?

If you would like more information about the project or if you need to speak to a member of the research team in an emergency please contact:

Contact telephone: (04) 23 188 247
Email: takecare@mcri.edu.au

If you have any concerns and/or complaints about the project, the way it is being conducted or your rights as a research participant, and would like to speak to someone independent of the project, please contact: Director, Research Ethics & Governance, The Royal Children’s Hospital Melbourne on telephone: (03) 9345 5044.
CONSENT FORM

HREC Project Number: 37100

Research Project Title: Concussion Essentials

Version Number: 8  Version Date: 23/09/2020

- I have read, or someone has read to me in a language that I understand, the information statement version listed above and I understand its contents.
- I believe I understand the purpose, extent and possible risks of my involvement in this project.
- I voluntarily consent to take part in this research project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that this project has been approved by The Royal Children’s Hospital Melbourne Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007) – including all updates.
- I understand I will receive a copy of this Information Statement and Consent Form.

OPTIONAL CONSENT

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| ☐    | ☐       | consent to the storage and use of my information in future ethically-approved research projects that are conducted at or closely affiliated with the Murdoch Children’s Research Institute

Participant Name

Participant Signature

Date

Name of Witness to Participant’s Signature

Witness Signature

Date

Declaration by researcher: I have explained the project to the participant who has signed above, and believe that they understand the purpose, extent and possible risks of their involvement in this project.

Research Team Member Name

Research Team Member Signature

Date

Note: All parties signing the Consent Form must date their own signature
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Participant Name: ____________________________
Participant Signature: ________________________
Date: ____________________________

Name of Witness to Participant’s Signature: ____________________________
Witness Signature: ________________________
Date: ____________________________

Declaration by researcher: I have explained the project to the participant who has signed above, and believe that they understand the purpose, extent and possible risks of their involvement in this project.

Research Team Member Name: ____________________________
Research Team Member Signature: ________________________
Date: ____________________________

Note: All parties signing the Consent Form must date their own signature.

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