

Participant Information and Consent Form: Minors

AUS-mTBI: designing and implementing novel health informatics approaches to improve outcomes for people with mild traumatic brain injury across Australia

Coordinating Principal Investigator:

Professor Melinda Fitzgerald (Curtin University)

Phone: 0467 729 300

Email: Lindy.fitzgerald@curtin.edu.au

1. Project Summary?

- Your child is being invited to participate in a research study because they have had a mild traumatic brain injury (that is, a concussion).
- Please read the information carefully and contact the research team or discuss your child's participation with your GP if you have any concerns.
- Your child's participation in this project would involve using the HeadCheck app or website to track their concussion symptoms and receive guidance to normal life e.g. family activities and events, sport, physical activity, or study after their concussion.
- This project is a collaboration between over 100 experts in concussion and their associated organisations across Australia.
- This project has received ethical approval from the Alfred Health Human Research Ethics Committee.
- The project is funded by the Medical Research Future Fund.

2. Why are we doing it?

- Following concussion, most people feel better in a few days or weeks
- A small number of people might continue to have persistent post-concussion symptoms (PPCS) including altered thinking, headache, dizziness and tiredness.
- It is currently not possible to know who will have persisting concussion symptoms.

This project aims to:

- i. Collect information via an app or website on factors that may predict of outcome following concussion to better understand whether a person with concussion will develop PPCS.
- ii. Use the results to tailor the in-app/website care recommendations to be more specific to an individual's symptoms and as a result, improve their recovery.

3. What will my child's participation in this project involve?

- You will be asked to provide consent on behalf of your child.
- You will be asked to provide information through an app or website about your child, the circumstances of their concussion injury, and their concussion symptoms.
 - Answering the questions about your child's injury will take between 10-15 minutes.
 - You will then be able to access a personalised recovery program for your child that will provide suggestions for daily activities to complete, based on their symptoms, to help their recovery.
- As your child recovers, the app or website will prompt you every few days to start with, and then fortnightly after your injury, to answer questions about your child's concussion symptoms, quality of life and whether they have returned to their regular activities until your child's symptoms resolve. These follow up questions will take approximately 10 minutes to complete.
- If your child's symptoms continue beyond 3 months after their concussion, you will be prompted to completed these same questions each month until their symptoms have resolved.

4. What are the benefits and risks of taking part to my child?

- Using the app and assisting your child to complete the recovery program is likely to benefit you and your child by learning about what their symptoms mean and having the app (or website) help them get back to daily activities.
- If your child enrolls before 31st December 2025, they will be eligible to win one of five \$500 prepaid Visa gift cards for recognition of their contribution. The gift card will be provided to the parent/guardian on behalf of the participating child.

- People who have a concussion in the future may benefit from the findings of this project through:
 - Health professionals being better able to predict who will recover quickly from a concussion and who won't.
 - The development of new concussion treatment strategies or research projects.

- There are no known risks associated with your child participating in this project.

- Data will be held in a secure, online platform and it is not anticipated that data breaches will occur. In the event of any privacy breach, you will be notified immediately by the research team.

- It is not anticipated that answering these questions will cause any distress. In the event that you or your child do feel distressed, information regarding assistance and telephone support services are linked within the HeadCheck app.

- If your child's symptoms do not improve or they show signs of getting worse, the app and website will have built in pathways to direct you to return to your child's GP or seek urgent medical attention.

- If your child continues to experience persistent symptoms, your child may be offered the opportunity to participate in further studies focusing on concussion treatments.

- The HeadCheck app is approved in Australia to help parents, first aiders, trainers and coaches recognise the signs and symptoms of concussion and monitor recovery of concussion in children, adolescents and adults. However, the device is not yet approved to be used with the changes made for this project, therefore, it is an experimental treatment for this study. This means that it must be re-tested to see if it is an effective device for concussion management.

5. *What will happen to information about my child?*

Your child's data is going to be highly secure because:

- Any information obtained for the purpose of this project that can identify your child will be kept confidential and securely stored in an online database.
- Your child's data will only be shared with your permission
 - However, you should be aware that should your child become involved in a criminal or civil case, in certain limited circumstances, a court of law may be persuaded to order disclosure of particular information relating to your child which would otherwise remain confidential.
- We will ensure that our security measures conform to national standards to prevent unauthorized access.
- All data used in the research will be kept safe and personal identification hidden on a special research platform.
- Only those involved in the research will be allowed to access your child's information.
- The results of this project will be published and/or presented in a variety of forums. Reports will be produced for public, government, clinical and academic audiences. These publications will help to inform the community about common trends in recovery and/or gaps that may exist in service provision.
- **No publication or report will ever contain any identifying information about your child.**
- All data will be safeguarded by State and Commonwealth privacy laws.
- In accordance with the Australia Privacy Act (1998) and other relevant laws, you have the right to request access to your child's information collected and stored by the research team. Please contact the project team member named at the end of this document if you would like to access your child's information.

Future use of your information

- Researchers may use non-identified, group data for future research projects. Any further research undertaken using this project's data will require ethical approval.
- Your child's data collected for this project will be stored on Monash University owned, secure and resilient infrastructure located in Australia, complying with global best practice data protection requirements. Your child's data will be subject to strict privacy and cyber security controls.
- Your child's data will be kept securely on Monash University platforms for 15 years, as per University research policies.
- Any future access to the AUS-mTBI data by other organisations or researchers will require ethics approvals and will be bound to the same State and Commonwealth legislations as well as the AUS-mTBI Data Access Policy.
- If your child has concussion symptoms that persist beyond usual recovery timeframes and you agree to being contacted about other concussion research projects, we may offer to connect you with other research groups.

6. Does my child have to participate in this study?

- Participation in this project is voluntary, and you have the right to withdraw your child from the project at any time. This will not affect ability to access the HeadCheck concussion recovery program for your child.
- If you choose to withdraw your child from the project but would like to continue using the app or website for your child's recovery, you will need to download the app again and re-enter their symptom and activity details, creating a new profile.
- If you choose to withdraw your child from the study, or they choose to withdraw themselves, personal information already collected will be retained, with your consent, to ensure that the results of the study can be measured properly, and the study data is as complete as possible. If you do not want your child's data retained, please inform the study team at the time of your child's withdrawal.

- If your child turns 18 whilst participating in this study, they will not be asked to provide consent again, however, are able to withdraw from the study at any time.

7. Contact Information

If you have any questions or concerns about this study, or would like a copy of the research findings once finalised, please contact the lead investigator, Professor Melinda Fitzgerald or 0467 729 300 or via email at lindy.fitzgerald@curtin.edu.au.

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC Office/Complaints contact person

Position: Complaints Officer, Office of Ethics & Research Governance, Alfred Health

Telephone: (03) 9076 3619

Email: research@alfred.org.au

Please quote the following project ID number: 267/23

Declaration by Participant's Parent/Guardian

I have read the Participant Information Sheet or someone has read it to me in a language that I understand. I understand the purposes, procedures, and risks of my child's involvement in the study.

I understand that I can withdraw my child's participation in this research at any time without affecting their future health care or engagement with the concussion recovery app.

****on-screen text****

AUS-mTBI Consent: Minors

I declare that I am over 18 years of age and a parent/guardian of the above named participant. I agree to my child's information being used for the AUS-mTBI study. I understand my child's name or my contact details will not be included in any publications and all information collected will remain confidential.

Yes

No

I agree to my child's non-identifiable information being used in future, ethically approved research studies.

Yes

No

If consent 'Yes' to AUS-mTBI study:

I agree to my child's information being maintained indefinitely for future, ethically approved research studies as part of the AUS-mTBI Registry database. I am aware that this may include other government agencies releasing information about my child's injury and treatment to the research team for research purposes. I understand that my child's name or contact details will not be included, and all information collected will remain confidential.

Yes

No

I agree to being contacted by the research team about possible intervention (treatment) studies if my child's concussion symptoms persist beyond 6 months

Yes

No

AUS-mTBI Withdrawal of Consent Form (Minors)

Parent/Guardian Declaration

I wish to withdraw my child's participation in the AUS-mTBI research project and understand that such withdrawal will not affect my child's routine treatment, relationship with their treating team, or my child's ability to gain advice about their recovery from the Headcheck app or website.

Ending my child's participation means:

- My child will no longer be contacted about this research study unless I need to be notified of a safety concern.
- Information about my child, including my child's health information, will no longer be collected.
- I understand that information obtained about my child prior to this withdrawal of consent will be kept and used in the study and may be used by researchers in future, ethically approved studies unless I specifically ask for my child's data to be removed from the database.
- I have not withdrawn my consent for my child's involvement in the AUS-mTBI Registry if it was previously provided. I understand that to withdraw my child's participation in the AUS-mTBI Registry, the Registry withdrawal formal must be completed separately (available via link in Headcheck app).

Please tick here to remove any previously collected information about my child from the study database

Name of Participant: _____

Name of Parent/Guardian: _____



Date: _____

*****END*****