

Participant Information and Consent Form: Adults

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

Coordinating Principal Investigator:

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1. Project Summary

- You are being invited to participate in a research project because you have had a mild traumatic brain injury (that is, a concussion).
- Please read the information carefully and contact the research team or discuss participation with your GP or a local health team if you have any concerns.
- Participation in this project will involve using the HeadCheck app or website to track your concussion symptoms and receive guidance to returning to normal life e.g. family activities and events, sport, work, physical activity, or study after your 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 Hospital 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 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 participation in this project involve?

- You will be asked to give your consent.
- You will be asked to provide information through an app or website about you, the circumstances around your injury, and your concussion symptoms.
 - Only the data that you input manually through your device will be collected for this research.
 - No data will be collected from your device camera, microphone, any integrated Bluetooth device.
 - Answering the questions about your injury will take between 10-15 minutes.
 - You will then be able to access a personalised recovery program that will give suggestions for daily activities to complete, based on your symptoms, to help your recovery.
- As you recover, the app or website will remind you every few days to start with, and then fortnightly after your injury, to complete questions about your concussion symptoms, your quality of life and whether you have returned to your regular activities until your symptoms have gone. These follow up questions should take approximately 10 minutes to complete.
- If your symptoms continue beyond 3 months after your concussion, you will be prompted to complete these same questions each month until your symptoms have resolved.

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

- If you use the app and complete the recovery program, you are likely to benefit by learning about what your symptoms mean, and having the app help you to getting back to daily activities.

- If you enrol before 30th June 2024, you will be eligible to win one of five \$1000 prepaid Visa gift cards for recognition of your contribution.
- 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 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 do feel distressed, information regarding assistance and telephone support services are linked within the HeadCheck app.
- If your symptoms do not improve or you show signs of getting worse, the app and website will have built in pathways to direct you to return to your GP or seek urgent medical attention.
- If you continue to experience persistent symptoms, you may be offered the opportunity to participate in further studies focusing on concussion treatments.
- The HeadCheck app in its current form 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 me?

Your data is going to be highly secure because:

- Any information obtained for the purpose of this project that can identify you will be kept confidential and securely stored in an online database.
- Your data will only be shared with your permission.
 - However, you should be aware that should you 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 you which would otherwise remain confidential.

- We will ensure that the project 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 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 you.**
- 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 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 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 data will be stored indefinitely on Monash University owned, secure and resilient infrastructure located in Australia, complying with global best practice data protection requirements. The project data will be subject to strict privacy and cyber security controls.
- Information collected for this project will be kept securely on Monash University platforms for 15 years, as per University research policies.
- Any future access to 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 you have concussion symptoms that persist beyond usual recovery timeframes and agree to being contacted about other concussion research projects, we may offer to connect you with other research groups.

6. Do I have to participate in this project to use the app?

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

Please [click here](#) to access the withdrawal form to be emailed to the research team.

7. Contact Information

If you have any questions or concerns about this project, 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

Participant Declaration of Consent

By consenting to participate in this project, I acknowledge that I have read and understand the information provided in this participant information sheet or someone has read it to me in a language that I understand.

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