PARTICIPANT INFORMATION SHEET

Project Title: Aotearoa Concussion Services Cost-Effectiveness Study (ACCESS)

Locality: Ethics Committee ref: 20/NTB/141
Principal Investigator: Dr. Braden Te Ao Contact Phone No. (09) 373.7999

You are invited to take part in a University of Auckland-led study about the effectiveness of concussion service care in improving health outcomes for people with mild traumatic brain injury (also known as a concussion or head injury). You have been invited because you were diagnosed with this condition in the last 12 months, are receiving care in a concussion service, and are aged at least 18 years old.

Whether or not you take part in this study is your choice. If you don’t want to take part, you don’t have to give a reason. Taking part, or not, won’t affect the care you receive from the concussion service or any other organisation that is supporting you. If you do want to take part in this study, but change your mind later, you can pull out at any time.

If you do take part, this will involve you taking part in three 30-40 minute interviews spread over 1-year, at time and place convenient to you. We will also ask your permission to access other information held for you by health and social support services. None of your information will be shared with other organisations providing care or support to you. More detail about taking part is set out below in ‘Important Information about taking part in this study’.

The Researchers
The research is being conducted and led by the University of Auckland. The researchers are Dr. Braden Te Ao, Professor Suzanne Barker-Collo, Dr. Richard Edlin, Associate Professor Matire Harwood, Associate Professor Alain Vandal, Dr. Lisa Walton (all University of Auckland), Professor Alice Theadom (Auckland University of Technology), and Natalie Hardaker (Accident Compensation Corporation). The research is funded by the Health Research Council of New Zealand. It is supported by Accident Compensation Corporation (ACC), and concussion clinics nationwide (e.g. ABI Rehabilitation, Proactive Four Corners of Health, and Active Plus).

What is this study about?
We want to find out if early presentation to a concussion service contributes to an earlier return to usual activities (e.g. work, education, etc.) as well as better health outcomes. We will recruit two groups of mild traumatic brain injury (mTBI) participants (1) those who have their first appointment at their concussion clinic within 40 days of being diagnosed, and (2) those who have their first appointment at a concussion clinic after 40 days after being diagnosed. We will collect the same information from both participant groups.

We also want to hear about people’s experiences of having a mild Traumatic Brain injury, the health and
support services they have used for this, and any costs/expenses they have had to meet. People with this condition commonly experience a range of ongoing symptoms including headaches, sleep problems, fatigue, problems with concentration and memory, sensitivity to light and noise, and feeling anxious and depressed. These symptoms can affect usual daily activities and overall quality of life.

Current treatment guidelines recommend specialised concussion services for the treatment of mTBI. ACC currently funds these services for patients and most people who receive this are referred by ACC or their usual doctor (GP). Understanding user experiences is essential for understanding if these services are effective in helping patients with an mTBI, and how we can improve these. Treatment guidelines recommend early access to such services. So for this study we also want to compare if early or later presentation to a concussion service for an mTBI makes a difference to patient outcomes.

**Important information about taking part in this study**

- Taking part in this study is voluntary (your choice). Taking part, or not, won’t affect any of your present or future care or support from any organisation providing health or social services for you.
- If you do decide to participate, a member of the research will telephone you to first confirm that you meet our eligibility criteria using a 10-minute screening document. Actual participation will involve you in two processes – taking part in a questionnaire 3 times over 1 year **AND** giving the research team permission to gather supplementary information held on government databases related to your mTBI/concussion. Both parts are necessary.
- **About the questionnaire:**
  - A member of the research team will interview you 3 times using a questionnaire. Each of the interviews will last 30-40 minutes (total time approximately 2 hours). You can choose to have this done by telephone, or in-person (e.g. by video call, or at your home).
  - The first interview would be soon after you agree to take part in the study. The following interviews would be approximately 3 months and 12 months later.
  - You can have a support person present if you wish, and where possible the interviewer will be of a similar ethnicity or heritage to you.
  - You will not have to answer any questions you don’t wish to and you can stop the interview at any time.
- **About the supplementary information that we need to gather about you:**
  - We need to gather information held on government databases relating your mTBI/concussion including your use of health, community, and social services.
  - This data is held on government databases including National Health Collections and ACC’s Collections.
  - This information will be gathered after you have completed all the questionnaires.
- More detail about the types of information we want to collect from you at interviews and from government databases is provided in the sections below.
- **Everyone who takes part in the study will receive a grocery/food or petrol voucher valued at $50.00 after completion of the 12-month interview**

**More about the types of information we want to collect for this study**

The ‘**What is this study about**’ section above gives details about the types of information that the questionnaires will ask you about directly. Nearly all of the questions come from NZ studies with patients
who have been diagnosed with an mTBI or similar condition. Some of the questions will ask about sensitive issues such as employment, mood, and relationships. We will treat all the information you provide as confidential.

Unfortunately, not all the detail we need to conduct this ‘cost-effectiveness’ study is held by participants. This is the reason we are asking participants to give permission for the research team to access supplementary mTBI injury related health service use information held by the Ministry of Health National Data Collections and ACC Data Collections (e.g. services used and costs for their mTBI injury involving hospitals, concussion clinic visits, primary care, and ACC), and from the national health and social service Integrated Data Infrastructure (IDI) database (e.g. employment status, social benefits received). We will then link together individual participant’s questionnaire data with the supplementary data to answer our research questions. Again, we will treat all this additional information as confidential.

Protecting your anonymity and confidentiality

We will undertake all reasonable steps to protect the privacy and confidentiality of participants in this study. We are establishing a data management and governance plan to guide data collection, and safety, privacy and confidentiality of all data we are collecting for this project (e.g. questionnaires and supplementary data) and any reports and publications. All information collected for this study will be stored on password protected and encrypted (locked) computer databases, or in locked cabinets at the University of Auckland. The only people with access to this information will be those authorised by the Principal Investigator. All study information will be shredded or erased after 10 years.

Specifically, to protect your identity and maintain confidentiality:

- We will remove your name from any electronic databases, and any reports or publications about this study.
- We will keep paper copies of any documents with your name, date of birth, and address written on them separate from other documents.
- Each participant will be given a personal unique identifier code that will be used on all paper documents and electronic files.
- To protect your confidentiality during the collection of supplementary detail from other organisations and data linkage, we will ensure that there are no personal identifiers (names, addresses) in electronic files sent to other organisations for this purpose or received from them. Also, all files will be exchanged using an encryption code.
- Any personal information that we collect about you from a questionnaire or supplementary information from any one organisation providing health or social support services to you will not be shared with another health or social support organisation.

What are the benefits of being involved with this study?

The benefits of taking part in this study is that it will allow you to discuss your experiences of having an mTBI. You will be able to discuss things that you think have been done well, things you still need help with, and things that could be (or could have been) done better. If you have not already done so, taking part in the study may prompt you to discuss your concerns with relevant services (e.g. the concussion service, your GP, ACC case manager). Importantly, this research aims to improve early access to expert services and support for people with mTBI – so that people receive the right services at the right time.

There are minimal risks for people taking part in this study. Trained research assistants will work with you to answer the participant questionnaires and will follow good and safe procedures outlined in a manual developed for this purpose. If participants or any family member feels unsafe, or they feel they have not been treated with respect and dignity, they can stop the interview. We encourage participants to raise any concerns with Braden Te Ao (Principal Investigator) or Lisa Walton (Project Manager) who will address these issues.
Can I change my mind and withdraw from the study?
Even if you agree to participate in the study you can change your mind and withdraw from the study at any time. This can be before the first interview, or before all three interviews are completed. If you withdraw at any point you can choose to allow, or not allow, us to use any information about you we have collected directly from you or from other organisations.

What will happen to findings from the questionnaire interviews and other sources of information?
Participants will be provided with a summary of study findings, if they would like this. Findings from the questionnaire interviews will feed into other information obtained from providers of services, and other sources. Reports of this study will be used to inform health and social service organisations involved in planning, funding, and providing services for people who had an mTBI, and those who care for them.

Where can I get more help if I need this after the interview(s)?
It is possible that taking part in the interviews may remind you about any concerns you have about your health condition or care, or concerns about your own needs that you feel have not been met. We suggest you raise these issues yourself with the concussion service and/or your usual doctor (GP) as these people will have the best advice. If you feel you have other concerns you could contact a Health and Disability Advocate (see contact details below).

Contact details for the Research Team
If you have any questions, concerns, or complaints about the study at any stage, please contact the research team at the University of Auckland. Braden Te Ao is the overall leader for the whole project and Lisa Walton is the Project Manager. Their phone and email contact details are set out below. *(Note: if telephoning, you may need to leave a message including a name and contact number so that we can call you back.)*

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<thead>
<tr>
<th>Name</th>
<th>Telephone</th>
<th>Email</th>
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<tbody>
<tr>
<td>Dr. Braden Te Ao</td>
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<td>Dr. Lisa Walton</td>
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<tr>
<td>ACCESS study direct</td>
<td>Freephone: 0800 222 237</td>
<td><a href="mailto:access.study@auckland.ac.nz">access.study@auckland.ac.nz</a></td>
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If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:
Telephone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

For Māori health support please contact: (details to be confirmed)
Name, position:
Telephone:
Email:

You can also contact the Health and Disability Ethics Committee (HDEC) that approved this study on:
Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz
Reference No. 20/NTB/141

**APPROVED BY THE HEALTH AND DISABILITY ETHICS COMMITTEE ON 14th September 2020 for three (3) years, Reference Number 20/NTB/141**

Aotearoa Concussion Service Cost Effectiveness Study (ACCESS). Participant Information Sheet, as at 22nd June 2021