Development of a Concussion Management Platform (Back2Play App) for Children and Youth: Bridging the Gap Between Research and Practice

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LETTER OF INFORMATION / CONSENT

Development of a Concussion Management Platform (Back2Play App) for Children and Youth: Bridging the Gap Between Research and Practice

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You are being invited to participate in this research study being conducted by Prof. Carol DeMatteo, because you have recently had a concussion. If you are acting as a substitute decision maker, you are being asked to provide informed consent on behalf of a person who is unable to provide consent for themselves. In this form, "you" refers to the person you are representing. If the participant gains the capacity to consent, your consent for them will end.

In order to decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate.

What is the study About?

The decision regarding return to activity following concussion is one of the most difficult and controversial areas in concussion management for adults and even more complicated for children and youth. The presentation of symptoms after concussion can have a significant impact on a child/youth's participation in daily life, including at school and in sport. Children and youth are at high risk for repeat injuries within a short period of time. We recently developed evidence-based child-and-youth-specific protocols for Return to Activity/ Return to School (RTA/RTS). In examining these guidelines, our team found that children/youth had difficulties following the protocols due to lack of

feedback and guidance. To address these issues the current study team has developed a comprehensive concussion management platform, The Back2Play App, that can monitor and evaluate symptoms as well as provide real-time activity data (i.e. heart rate) to guide youth on how to adjust their activity to minimize symptom exacerbation.

The present study will explore whether The Back2Play App, available on mobile devices, reduces time to symptom resolution and time to return to full activity/school and prevents reinjury within three months of initial injury in youth aged 10-18 years with concussive injury as compared to Usual Care.

Outcomes of the study will include time to symptom resolution, risk of repeat injuries, length of time to return to play and school and parents' and youth's use and perceptions of the new Back2Play App. Electronic activity monitoring devices (Apple Watch) will be used to provide both compliance with guidelines and health information.

What is the purpose of this study?
We want to determine if The Back2Play App helps youth with concussion reduce the time to symptom resolution and return to full activity and prevent reinjury. To do so, The Back2Play App will be randomly assigned to 80 youth and families while 80 participants are given Usual Care (usually guidelines in a handout format) to determine if The App was as helpful in guiding as what would typically be provided for guiding them through the RTA/RTS protocols.

What does randomized mean?
Randomization can be compared to the act of shuffling cards and the card chosen is done so by chance. If you choose to participate, you will be provided a study number that the computer has randomly assigned to The App group or the Usual Care group so that you have a 50/50 chance of being in either group. Once you have been assigned to a group, it cannot be changed.

How will I participate during COVID-19?
Participants can take part in the study in a hybrid model using both Zoom and/or in person components. All interactions with research staff will adhere to McMaster's COVID-19 guidelines as well as government recommendations.

How will I be involved in this study?
By participating in this study you do not give up any rights to which you may be entitled under the law. If you consent to participate in the study, we will ask you to do the following things depending on which group you have been randomly assigned to:

Participants who have been randomly assigned to <u>The App group at The Emergency Department of McMaster Children's Hospital</u> will be:

- Loaned an Apple watch to use for the duration of the study and an iPhone (if they do not have one or it is not an iPhone 6 or later).
- Helped to download The Back2Play App and The B2P BrainGames App onto their iPhone and the Apple Watch by a Research Assistant. This will take place either

on the day you are admitted to the ED or 2 days following your giving consent to participate.

- Helped to pair the Apple watch with their phone.
- Asked to answer questions about their concussion and personal history by the Research Assistant at The Emergency Department or the next day over a 10-15 minute Zoom call or phone interview.
- Asked by The App to complete 3 symptoms surveys per day on The Back2Play App (Morning, Afternoon and Evening) until 2 days following symptom resolution. Each survey takes about 5 minutes to complete at maximum.
- Asked to complete 10-minutes of games on the B2P Brain Games App (i.e. neuropsychological screen) about once a week.
- Complete a Follow Up survey as well as the System Usability Scale (SUS) (Appendix) 2 days following symptom resolution. The Follow Up survey will assess your experience with The Back2Play App as well as if you have experienced a repeat injury and a final symptom survey. The survey and the SUS take about 10 minutes to complete at maximum.
- Scheduled for a 20–30-minute Zoom Follow Up meeting 2 days after symptom resolution or after a maximum of 3 months of using The App. Here we will ask participants questions regarding appeal of The App, ease of use, clarity, feature of colour, voice, etc; Also their perceptions of how well the App guided them through their recovery. Did they agree with classifications and notifications, did they understand the guidelines? This Zoom visit will be recorded and saved to a secure, password encrypted study computer. Participants will be asked to delete the App from their phone during this interview.
- After using The Back2Play App, participants will be supplied with a FedEx transit envelope and will be asked to mail back the Apple Watch and iPhone to the research team.
- 3 months following study enrollment, participants will be asked to complete a 5-minute survey about reinjury.

Participants who have been randomly assigned to <u>The Usual Care group at The Emergency Department of McMaster Children's Hospital</u> will:

- Receive the normal course of care provided by that Emergency Department (which typically involves education regarding how to safely return to activity and school as well as any resources and hand-outs typically given).
- Complete symptom surveys and a cognitive scale every 24 hours which will be sent to them through email by REDCap. Each survey takes about 5 minutes to complete at maximum and participants will receive a reminder email to complete the surveys everyday.
- Report their stage of RTA/RTS every 24 hours on REDCap until 2 days following symptom resolution.
- Attend a scheduled 20-30-minute Zoom session 2 days after symptom resolution or after 3 months of participation for those who do not achieve symptom resolution. Participants will be asked questions regarding their knowledge of and ability to follow the paper guidelines or advice they were given and if they have

had a repeat head injury. This Zoom visit will be recorded and saved to a secure, password encrypted study computer.
- 3 months following study enrollment, participants will be asked to complete a 5-minute survey about reinjury.

Participants who are recruited from other sources besides the hospital will:

- Be contacted by the Research Team upon consent to contact from community.
- Determine eligibility, review consent and agree by phone or zoom with signed consent scanned.
- Be randomly assigned to App or Usual Care groups.
- Those in the App group would then come into the University to receive and set up their devices (as above). Those in the usual care group would be instructed over phone or zoom about the surveys they will be expected to complete.

What are the risks?
Some participants may experience worsening of post-concussion symptoms during the completion of testing The Back2Play App due to physical or cognitive exertion or screen time on The App (e.g. headache, dizziness, nausea, etc.). In the event of worsening post-concussion symptoms, participants will be informed to stop activity and App use immediately and resume again only after a minimum period of 24 hours of rest and the resolution of symptoms. If symptoms do not resolve, you will be asked to notify your family physician. If you do not want to continue with the testing, there will be no negative consequences. In addition, it is not clear if those using The App will improve more or less quickly or have more or less head injuries than those in the Usual Care group. Surveys will be checked periodically for participants in both groups.

What are the benefits for me and my family and for society?
Participants may not receive any benefit from participating in the study but this research may help devise better management plans for other concussion patients in the future.

How many people will be in this study?
The Back2Play App randomized controlled trial will involve 160 youth 10-18 years old who have had a concussion, recruited from the Hamilton Wentworth Catholic District School Board (HWCDSB), McMaster Children's Hospital, Montreal Children's Hospital, concussion clinics and sports teams across Hamilton and the Greater Toronto Area.

How do I agree to participate?
If you want to participate in the study, a member of the Research Team will review this form with you on Zoom, in person or over the phone. If consent is obtained over Zoom, the forms will be signed over email indicating your consent. Zoom is an externally hosted cloud-based service. A link to their privacy policy is available here (https://zoom.us/privacy-and-legal). While the Hamilton Integrated Research Ethics Board has approved using Zoom to collect data for this study, there is a small risk of a privacy breach for data collected on Zoom. If you are concerned about using Zoom, we would be happy to make alternative arrangements for you to participate, perhaps via

telephone. We will also follow this verbal consent with having you sign hard copies electronically. Please talk to the research team if you have any questions.

What if I change my mind about being in the study?
Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time without affecting your care. You may also refuse to answer any questions and still remain in the study. Choosing not to participate in this study will in no way affect your care or treatment.

If you decide to leave the study, those in the App group will be directed to unpair the watch from their personal iPhone and delete the App. The information that was collected before you left the study will still be used, but you do have the option to remove it from the study.
If you choose to leave the study, you are still provided with the child post-concussion protocols, in paper-format to follow, as you and your physician deem necessary. Just contact the Study Coordinator as noted at the bottom of this form to withdraw.

What information will be kept private?
All the information that we collect about you will be kept private. Your data will not be shared with anyone except with your consent or as required by law. If you agree to share information with your parents via The App, it will be shared only with your prior consent. All personal information such as your name, address, and phone number, will be removed from the data and will be replaced with a number. A list linking the number with your name will be kept in a secure place, separate from your file. The data, with identifying information removed will be securely stored in a locked office in the research offices at CanChild, the Centre for Childhood Disability Research.

The App only collects data that will be used for the study. This includes biophysical data such as heart rate and movement. The App will stop collecting data 2 days after your completion of the study and you will be asked to delete The App and send devices back to The Back2Play team. Confidential data will be used for machine learning and commercialization.

If the results of the study are published, your name will not be used. All data collected from all participants will be combined to form one large data set. As a result, individual participants will not be identified.

The information that is collected for the study will be kept in a locked and secure area by the researchers for 10 years. Only the study team or the people or groups listed below will be allowed to look at your records.

Representatives of Hamilton Integrated Research Ethics Board and this institution and affiliated sites may look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines. Data collected using the Apple watch resides on the Apple servers and no assurance can be made about its confidentiality or that it will

only be used for research purposes. Data collected by The App about your recovery may be used to build further predictions for The App to rely on in future iterations.

Will I be paid to participate in this study?

If you participate in the testing of The Back2Play App Study, you will receive a $20 generic gift card and if you use your own cellular device, you will receive $25 in compensation for data usage. Parking vouchers for days of assessment visits to McMaster University will be provided to each participant. We will also be giving away 10 of the Apple Watches used in the study. You may be eligible to participate in a lottery for these used Apple watch SE's at the end of the study. All participants who complete 80% of their surveys will be entered into this draw, giving participants an approximately 1 in 16 chance of winning a watch. It is possible that the research conducted using your study data may eventually lead to or support the development of commercial products. There are no plans to provide payment to you if this happens.

Questions about the study

If you have questions or need more information about the study itself, please contact:

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CONSENT

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I have read the preceding information thoroughly. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I understand that I will receive a signed copy of this form.

Signature of Participant/ Substitute Decision-Maker	**PRINTED NAME**	**Date**

If consent is provided by Substitute Decision Maker _____ **PRINTED NAME of Participant**

<u>Person obtaining consent</u>:

I have discussed this study in detail with the participant. I believe the participant understands what is involved in this Study.

Name, Role in Study	**Signature**	**Date**

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HIREB). The HIREB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions regarding your rights as a research participant, please contact the office of HIREB at 905.521.2100 x 42013.