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

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PROTOCOL

Title of Study:	Development of a Concussion Management Platform (Back2Play App) for Children and Youth: Bridging the Gap Between Research and Practice
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1. STUDY PURPOSE AND RATIONALE

Katie was an honour roll high school student with a passion for high level competitive basketball and won many championships with her school team. Over the course of four years, Katie sustained four concussions while playing basketball. She has no memory of any of her injuries. In addition, she suffered from daily headaches, nausea, vomiting, dizziness, fatigue, fogginess, inability to concentrate and poor memory. Her prolonged symptoms caused Katie to miss school, increasing her anxiety around falling behind, declining grades, and acceptance to university. Due to a lack of resources and supports available, Katie's parents were at a loss as to how they could help her recover and manage her symptoms. She had to wait months for an appointment with a specialist and felt hopeless that she would ever feel like herself again. With limited guidance, Katie engaged in physical and cognitive activity too soon after injury, ultimately contributing to prolonged and worsening symptoms. Her symptoms caused her to withdraw from basketball, leading to anxiety, depression and social isolation. Three years after her injuries, Katie still deals with some of the lingering concussion symptoms. Her headaches are frequent and severe, while memory and concentration interfere daily in her scholastic achievement. Katie, a thoughtful and articulate young adult, wishes that she had had more specific daily guidance when recovering from her concussion and believes if she did, she may have had a quicker and less stressful recovery.

The decision regarding return to activity following concussion remains one of the most difficult and controversial areas in concussion management - with significant repercussions as in Katie's case.
Adhering to guidelines for safe return to activity/ school is a challenge for youth. Lack of adherence can contribute to prolonged recovery and repeat injuries. Youth like Katie who sustain a concussion are predominantly provided with management strategies based on professional consensus Return to Activity (RTA) and Return to School (RTS) protocols, with most referencing the Berlin Consensus Statement (2017).[1] These protocols were designed for adult athletes[1] and very little monitoring occurs to inform how or when a child/youth should progress through the stages. It is notable to the reader that the term youth will be applied throughout this document to define our population of interest which includes those between the ages of 10 and 18.

Our research team has made significant advances in the management of concussion in youth by creating evidence-based child-and-youth-specific protocols for RTA and RTS (www.canchild.ca).[2] In evaluating these guidelines, our team found that youth had difficulties following the protocols due to lack of feedback and guidance.[3] Further, results from our community-based study, which included the partnering school board, showed much variation in the implementation of the concussion protocols in youth amateur sport.[4]

What is needed now – what will help youth like Katie – is **a comprehensive concussion management platform** that can monitor and evaluate symptoms, real-time activity monitoring that guide youth on how to adjust activity to minimize symptom exacerbation. The aim of this project is to develop a new concussion management platform (Back2Play App), which will be available to youth post-concussion via mobile device. The platform will guide youth through the revised CanChild RTA and RTS Protocols (2018)[2]; include real-time monitoring of biological variables including heart rate, movement, symptoms, and cognitive activity; as well as incorporate new evidence on the balance of rest and activity from the CIHR funded 'Back to Play'[2] Study.

Research Question
Does a newly developed interactive Back2Play App, available on mobile devices, reduce time to symptom resolution and return to full activity and prevent reinjury 3 months after initial injury in youth aged 10-18 years with concussive injury as compared to usual care?

Hypothesis - We hypothesize that using the mobile health platform (Back2Play App) device will improve adherence to management strategies and will result in quicker recovery (defined as a quicker return to activity and school without symptom exacerbation, minimize development of Post-Concussion Syndrome (PCS) (greater

than 1-month symptom duration post injury) and prevent repeat injuries in the early vulnerable post-concussive period.

This project will occur in three phases; Phase 1: App Development, Phase 2: Usability Testing, and Phase 3; Feasibility RCT. **This application is for Phase 3 of the Back2Play App study.** Phase 1 and 2 were previously approved (#7393). The study will explore whether a newly developed 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.

Secondary objectives of this study will be:

- ☐ To conduct a multicentre Randomized Control Trial (RCT) comparing The Back2Play App to Usual Care with our partners at Montreal Children's Hospital (MCH), McMaster Children's Hospital, David Braley Sports Clinic (DBSC) and other clinics and community partners
- ☐ To evaluate through survey and interview, the perceptions of The Back2Play App from parents and youth.
- ☐ To explore commercialization of the new product.

Novelty and Significance of the Research - Most existing concussion management apps aim to provide education and some method for recording and tracking symptoms. These apps are information dense, lack user interaction and fail to integrate child/youth patterns of activity with symptom exacerbation to provide guidance about RTA and RTS based on evidence-based guidelines. By creating The Back2Play App that incorporates and streamlines key aspects of concussion management and monitoring, we will provide youth and their families with more autonomy and understanding of their recovery trajectories, with the goal of increasing overall adherence.

Return to activity/school is about (i) having adequate recovery time to eliminate or decrease symptoms and (ii) adhering to guidelines that gradually increase the amount and level of physical and mental activity to control symptom exacerbation[1, 5-9]. Activity monitoring through accelerometry and symptom tracking through the Post-Concussion Symptom Scale (PCSS)[10], combined with management protocols that give parameters for these would provide individualized feedback that is time sensitive. This mobile application would represent advances in individual data collection and adherence monitoring, while suggesting alternate activities based on clinically developed RTA/RTS Guidelines. The Back2Play App will be tested and refined with youth with concussion providing a realistic measure of clinical utility as well as desirability and approval by youth. The App includes a machine learning component that is currently observatory in nature, and for the purposes of the current study, will not be used to provide feedback to users.

Development of such techniques could provide insight as to how using these new methods may be incorporated into return to activity decision-making, which at present is subjectively decided by coaches, clinicians and parents. We believe these new methods of evaluation will provide not only the foundation of future research, but also information with immediate clinical utility. **The Back2Play App is not meant to replace medical management but to be a safe adjunct. Long-term, we aim to change the overall management and outcomes of childhood concussion.** The Back2Play App will have the potential to alter the current landscape of pediatric concussion management and research.

This ethics application builds on existing work and previously approved phases (#7393) from our 3-phase project:

Phase 1: We developed The Back2Play App in English and French. The App can monitor concussion symptoms, physical and cognitive activity level as well as the stage of the RTA/RTS Guidelines to assist in managing concussion recovery in children and youth. During this phase, we had 2 participants, youth with concussion, participate in User Experience testing sessions at the Institute of Applied Health Sciences at McMaster University. User Experience testing sessions are important in the technology industry because they assess the customer's response to a prototype of a product. We asked participants to use the Back2Play App on an iPhone and Apple Watch for 1 week and give us feedback on our App. Following User Experience, the App development team made improvements (extending survey times, language, use of colours) to ensure functionality and ease of use.

Phase 2: In this phase we pilot tested the The Back2Play App with youth. Youth were recruited from the Hamilton Wentworth Catholic District School Board (HWCDSB), McMaster Children's Hospital, Montreal Children's Hospital and Concussion clinics within the community. Unfortunately, because of COVID-19 restrictions the number of youth with concussions was low and a total of 17 participants were enrolled in this portion of the study. The main goal of the pilot was to test the App's content and usability at home and school with youth and get feedback to redevelop it. Overall youth reported a high satisfaction rate with The App. The System Usability Scale (SUS), which is a 10 item questionnaire administered to participants was used due to it's ease in evaluating software. On the SUS, a mean of 70% and median of 75% was achieved. The SUS reports that 68% is an average score and anything below that may require redevelopment. Youth also gave qualitative feedback on timing of surveys and troubleshooting issues which are currently being updated in the App.

We were also collecting data to develop machine learning algorithms that will be embedded within the Back2Play App prior to Stage 3. This algorithm will be tested and further trained to understand what stage of RTA/RTS the youth is in based on their symptom level, heart rate and movement data. A support vector machine classification algorithm was built using data from the pilot. Because enrollment was so low, the stages of guidelines were collapsed and the model currently predicts Stage 2, 3, 4 and 5 of RTA and 2, 3, and 4 of RTS. The architecture of this algorithm is sound but the predictive capabilities need more work, thus the algorithm will sit on the phone in the background and predictions will be sent directly to the B2P database. No information from the

algorithm will be shared with participants or used by The App to provide guidance through notifications.

Phase 3: The goal of Phase 3 is to conduct an RCT with our partners (Montreal Children's Hospital, McMaster Children's Hospital) comparing the effectiveness of the innovative Back2Play App versus Usual Care. We will assess whether The Back2Play App shortens the duration and intensity of post-concussion symptoms and prevents repeat injury in youth post- concussion. To do so we will evaluate:

1) Total symptoms, symptom severity and duration of symptoms.
2) Time to symptom resolution.
3) Risk for repeat head injuries within three months of initial injury.

2. BACKGROUND

Concussion, also referred to as mild traumatic brain injury (MTBI), is a major public health concern. Despite increased recognition of the serious health impacts of concussion, the number of injuries is rising in both Canada and the United States.[1] The presentation of symptoms after a concussion can have a significant impact on a youth's participation in daily life, including at school and in sport.

Concussion is a common child/youth health problem. In Canada, an estimated 15,970 patients presented to emergency departments (ED) with a sport-related head injury, including concussion, in 2011/12.[11] Among children and youth aged 5-18, there was a reported 42-47% increase in the proportion of head injuries relative to all other injuries in football, soccer and ice hockey between 2004 and 2014.[12] The actual number of concussion incidents is believed to be even higher given that many injuries go unreported. In a prospective Canadian study, Echlin *et al.*[13] observed an incidence of 21.5 concussions per 100 athlete exposures.

Concussion in children presents with a range of severity and results in short and long-term physical (e.g., headache, nausea, balance problems, dizziness, visual problems, fatigue), cognitive (e.g., feeling mentally 'foggy', difficulty concentrating or remembering), emotional/ behavioural (e.g., irritability, sadness, nervousness, anxiety) and sleep dysregulation sequelae which are collectively known as Post-Concussion Syndrome (PCS).[14-16] These symptoms are usually aggravated by physical and cognitive exertion if the child/youth has not fully recovered. Barlow *et al.*[17] note that diagnostic criteria for PCS may not vary in the type but in number and/or duration of symptoms present. This epidemiologic study from Alberta, Canada[17] confirmed that 59% of children/youth continued to be symptomatic one-month post-injury, 14% of children remained symptomatic three months post-injury and 2.3% were still symptomatic at one year. These results are congruent with data collected at the Acquired Brain Injury (ABI) Follow-Up Clinic at McMaster Children's Hospital (MCH). Here, 47% of children/youth still had 4

symptoms or more at 1 month post concussive injury. There is now a prediction risk score for PCS[18] which helps clinicians determine at presentation which children will go onto have PCS or symptoms past one month. All children/youth still must be monitored to determine if their symptoms resolve early or if they are among the 50% of children/youth at risk for symptoms lasting greater than one month, or one of the 13% that are symptomatic beyond three months post-injury. There is now a growing body of evidence to show that with education, comprehensive assessment and rehabilitation, symptom resolution may occur sooner and secondary problems like depression and school failure can be prevented.[19]

Multiple concussions are common in the pediatric population

Swaine et al.[20] found that concussed children are twice as likely to receive a subsequent head injury within 12 months. Moreover, more than 30% of high school athletes have been shown to sustain multiple head injuries.[21-22] Greater than 34% of children who received service at the ABI Follow-Up Clinic at MCH had experienced multiple concussions, with 17% experiencing three or more injuries.

Children who have sustained multiple concussions often have prolonged and severe symptoms including learning difficulties, behavioural problems, debilitating headaches, visual problems, and impaired memory.[23-25] Concussion often results in substantial long-term cognitive and behavioural disturbances that can have significant impact on the quality of life of individuals.[26-27] Our own research supports these findings as we found that children with mild injuries had decreased quality of life and neuropsychological impairment at five years post-injury compared to norms for age.[28] This evidence, in combination with the growing body of knowledge surrounding chronic traumatic encephalopathy (CTE) (where degeneration has been demonstrated in the brains of athletes who have had multiple concussions, some as early as 18 years of age[29-30]), commands us to **prevent** these repetitive injuries even though we may not yet fully understand the mechanisms and individual propensity to this debilitating condition.

Current approaches to concussion management have limitations

The Berlin Consensus 2016 Concussion in Sport Group (CISG)[1], which recently updated The Zurich Consensus[31], has provided guidelines for return to play for adult athletes which major sport and prevention institutions are readily adopting. These consensus statements were originally designed to provide general recommendations for the management of sport concussion in adults, with the pediatric population being considered in subsequent more recent versions.

While children and youth do present with similar post-concussion symptoms as adults, several investigators and The Berlin Consensus[1] have noted the need for a more conservative approach for their concussion management due to the unique physiological

make-up among the pediatric patients. [32-34]The CanChild Protocols for Concussion Management for children and youth 5-18 years[35-37] used in this proposed study were developed with reference to the consensus statements.[1] The CanChild protocols highlight the need for graduated RTA and RTS management strategies that reflect the pattern of recovery that is unique to each child/youth. Focusing on an individual's unique pattern of recovery may better reflect the complicated course of healing that requires more than a 'one size fits all' set of recommendations.

There are five stages in the CanChild RTS protocol[2] and six stages in the RTA protocol.[2] In these protocols, all children/youth are advised that there can be no high-level physical activity or contact sport while symptoms are present. However, 'rest' does not equate to social isolation or sensory deprivation. Daily activities that can be tolerated for each stage of recovery, without symptom exacerbation, are identified in the Activity Suggestions supplement that accompany the protocols, both of which are available on the CanChild website.[2] Families often find it difficult to gauge the appropriate amount of activity, including cognitive effort, for their child/youth's stage of recovery. The therapeutic goal in managing concussion recovery is to find the individual's level of cognitive and physical exertion that promotes healing which is the focus of our proposed Back2Play App. This graded approach was highlighted in a recent systematic review comparing the difference in concussion management in children/youth versus adults that was part of the CISG 2016 meeting in Berlin.[1] Importantly, this systematic review identified the need for an effective pediatric specific concussion management protocol.[38]

Current Concussion Management Platforms

Very little research exists on the use of concussion management platforms for treatment/prevention. A total of 5 articles[39-43] were retrieved from the PubMed database. As noted earlier, the main goal of these apps was to provide education and some method for recording and tracking symptoms. The Self-Monitoring Activity-Restriction and Relaxation Treatment - SMART provides recommendations for individualized symptom management, activity restrictions, guidance, stress management, relaxation and problem-solving skills following concussion. The Brain 101: The Concussion Playbook is purely a web-based education tool designed for sports-related concussion training. All studies had small sample sizes.

Back2Play App

The Back2Play App was developed in phase 1 of this project, to capture self reported symptoms and stages of recovery that youth indicate by filling in daily surveys and combine these with biological/activity data to track progress and give feedback about their recovery from concussion based from currently existing published guidelines. Accelerometry and heart rate data are collected through the Apple watch and sent to the API as well so that real time notifications can be given that may help youth adhere to the RTA/RTS guidelines. All notifications are based on published evidence-based guidelines used in clinical practice.

(https://canchild.ca/system/tenon/assets/attachments/000/002/642/original/Return_to_Activity_Guideline_WEB_1__Reference.pdf).

Rules, precedingly referred to as 'business rules', were developed for in App notifications that follow the guidance of the RTA/RTS protocols for progression through the stages (Appendix1.1) Symptoms, self reported stages and activities are measured daily in the morning, afternoon and evening. A summary of these surveys is found in appendix 1.2. The home screen of the App (appendix 1.3) summarizes the next survey time, current stage of return to school and activity the youth is reporting that day and the activity minute goals (based on their stage of recovery) and how many activity minutes are completed. Icons at the bottom direct users to 1) a summary page that will show this information as well as a graph of their current symptoms, 2) a charts page which has several graphs of their progress (symptoms, stages, heart rate and activity minutes), 3) resources including the CanChild guidelines for concussion recovery, symptom strata (or the type of recovery pattern they may be following), the playsafe cards for individual sport specific strategies and a list of activity suggestions for each stage of recovery and 4) a contact us page which gives the Research Team concuss@mcmaster.ca and Principal investigator contact info as well as a form for troubleshooting help. When youth fill out the surveys, if 2 or more symptoms are worse, a pop up option of texting or emailing the participant's parent appears (appendix 1.3) Notifications are also sent to youth who exceed their activity goals and the Back2Play App will send a cautionary message "You are doing too much!" if their heart rate goes above 180.

Encouraging notifications are also programmed with business rules if participants stay in the same stage for extended periods or if their symptoms get worst.

A complimentary App was developed by Dr. Geoff Hall of our investigator team. This Brain Games App was designed to screen some typical neurocognitive functions affected by concussion. There are 5 "games" that take about 10 minutes to complete. These include 1) finger-tapping, 2) divided attention, 3) memory for designs, 4) tracing and 5) face match. An 'in App notification' is triggered by the youth recording a progression in their RTS stage. "Let's do a brain teaser! Sign into The Back2Play Brain Games App for your brain game then complete your symptom survey!" If the challenging tasks result in increased symptoms, The App notifies them "The brain game can be hard, stay at this stage if you need too!"

These tasks may give the user some indication of readiness to move on in their recovery.

3. METHODS

Description of Population and Sample

Our population consists of male and female youth aged 10-18 years that have been diagnosed with a concussion by a physician. Youth presenting to the David Braley Clinic, McMaster Children's Hospital, HWCDSB, Montreal Children's Hospital or physicians in the community will be randomly assigned to the intervention or control groups.

A clinically significant effect of 10% decrease in repeat head injury and 10% decrease in recovery time would be of interest. The sample size calculation was done using parameters with a two sided significance of 0.05 and a power of 0.8 and based on our primary outcome of repeat head injury which is a binomial variable. Our anticipated incidence rate was compared to two rates of incidence in clinical settings and in the literature:

- 16% rate common in the literature
- our anticipated 2% rate with adherence to protocols (from previous B2P study) N=128
- 37% rate from concussion clinic at MCH and
- 13% rate of our pilot data N=100.

The larger number will be sought (sample size takes into consideration 20% refusal rate and loss to follow up) therefore we will recruit N=160. With an average of 25-30 new cases per month from the sources outlined above, 60% consent rate, and 12 months recruitment, it is feasible to attain this sample of youth.

4. INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria

Youth aged 10-18 at the time of injury will be included in this proposal. Youth must have had an impact to the head or body and diagnosed with a concussion by a physician. The youth must be symptomatic on admission to the study, and be within the first month of their initial injury. In addition, youth and their parents/guardians must be able to understand and complete questionnaires in English or French.

Exclusion criteria: Youth will be excluded from the study if they 1) have a confirmed significant brain injury requiring resuscitation, 2) were admitted to the pediatric critical care unit or surgical intervention, and 3) if they suffered a concussion but are no longer symptomatic, 4) they have been admitted to the PICU and 5) have been diagnosed with a developmental disability.

5. HOW SUBJECTS WILL BE RECRUITED

For Phase 3 of the Back2Play App Development, youth from McMaster Children's Hospital and Montreal Children's Hospital will be recruited. Both McMaster Children's Hospital and Montreal Children's Hospital have Research Assistants on staff that will ask if potential recruits would like to hear more about the study. A study information letter will be provided to those who are interested. Consent and randomization can occur in the ED with Research Assistants using an online randomization system (https://www.random.org/lists/). If parents want time to consider whether they wish to participate, the overview of the details of the project with the Research Coordinator's contact information will be sent home with them. If later interested, they can contact the Research Co-ordinator who will arrange a time to review

the consent and possible assent form. Forms outline the project details, explain what participation involves, and seek to obtain written consent/assent.

The randomization process will be shared with participants. They will be informed that, due to the nature of the project, they may or may not get to use The Back2Play App. If a youth is not provided with The Back2Play App, they will be provided the Usual Care. Usual care often includes guidelines or protocols to help youth safely return to activity and school.

Participants will also be recruited from HWCDS, concussion clinics and from our Knowledge Translation partners in the Hamilton and Burlington community. The incidence of concussion has been low to due COVID-19 provincial restrictions and so we must expand our recruitment efforts. Principles/Teachers as well as Coaches and Athletic trainers will be given information about The Back2Play App Study. If a youth with a diagnosed concussion is identified, the youth and their families will be provided a letter of information by their Principal/Teacher/Coach or Athletic trainer. This letter will encourage the youth and/or their family to contact the Research Coordinator about The Back2Play App Study. Alternatively, the Principal/Teacher/Coach or Athletic trainer will be provided a contact form (Appendix 1.4) to collect the contact information of the youth their family so that the Research Team can contact the interested participants directly. Only youth/their families who consent to provide their information to their Principal/Teacher/Coach or Athletic trainer will be contacted directly using the Phone/E-mail script, whichever they prefer.

6. PROCEDURES

* COVID-19 restrictions, if applicable: All interactions for the RCT with research staff will adhere to McMaster University's COVID-19 guidelines as well as government recommendations/protocols. As such, participants will be provided a combination of In Person/Zoom visits. Consent will most often be in person at the hospitals with research staff but if participants from the community choose to review consent over Zoom, they will be asked to sign consents through REDCap during the meeting. Zoom is an externally hosted cloud-based service (https://zoom.us/privacy-and-legal). Participants will be informed of the small risk of a privacy breach for data collected on Zoom. Participants will then be encouraged to express their concerns about using Zoom and be offered the alternative opportunity to participate via phone. An electronic copy of the consent or assent forms will be signed by participants on REDCap.

At the consent visit, regardless of method and site, participants will be fully informed of the protocol for each arm of the study (Usual Care and App group). Participants will also be informed of their chance (50%) of being assigned to either group. Due to the nature of the study participants and researchers are unable to be blinded to their study condition. Once consent is obtained, participants will be randomized to The Usual Care or The App group using computer generated codes. Those in The App group may be given their devices at the ED. Alternatively, if they can't stay for this they can come into The Institute for Applied Health Sciences (IAHS) within 2 days of consent to receive devices and download the App. If a participant is out of reasonable range to visit, devices may be mailed to them via FedEx within 1 day of providing consent and a Zoom meeting arranged to help download The App. If participants do not have an

iPhone above version 6, they will be provided an iPhone and an Apple Watch. They may choose to use their own iPhone if they have one with the appropriate model number. Participants will be informed that all devices supplied must be returned at the end of the study period.

7. INTERVENTIONS

Participants randomized to the control group will be provided Usual Care which often is some type of gradual return guidelines the practice (ED, General Practitioner) subscribes to. These are usually provided in a paper format for the patient to take home. Participants in the Usual Care group will complete symptom surveys every 24 hours via REDCap. The Back2Play App requests symptom surveys be done 3 times daily (quickly done on the watch or phone). The Back2play App also asks users to go to the BrainGames App when participants indicate they are ready to progress to the next stage of RTS in the guidelines. In The BrainGames App they can complete 5 neuropsychological tasks that provide feedback about their readiness to progress. These tasks are not available for those in the Usual Care group.

Surveys about cognitive and physical activities engaged in as well as the participants self-rating of cognitive activity level (1-5) and stage of recovery (1-5/6) are done on a daily basis by both groups.

Participants who have been randomized to the App group will be asked to:

- Download The Back2Play App and The B2P BrainGames App on their iPhone and the Apple Watch provided either at the ED or at a scheduled baseline visit (within 2 days of concussion).
- Pair the Apple Watch to their iPhone and wear an Apple Watch for the duration of the study.
- Complete the initial post-concussion symptom survey on the App with the Research Assistant and receive orientation to The Back2Play App.
- Complete 3 symptom surveys per day on The Back2Play App (Morning, Afternoon and Evening) and daily surveys about cognitive and physical activities as well as self-rating of participants' own cognitive level of activity and stage of concussion recovery until 2 days following symptom resolution.
- Complete games on the B2P BrainGames App (i.e. matching games) which are suggested whenever the participant moves up a stage in RTS Protocol.
- Attend a 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 about their perceptions of how well The App guided them through their recovery. Did they agree with classifications and notifications, did they understand the guidelines as well as questions about any other interventions they may have received. This Zoom visit will be recorded and saved to a secure, password encrypted study computer.

- Complete the (SUS) after they have finished using the App (Appendix 1.5). Participate in a Follow Up interview (Appendix 1.6) which will assess the youth's experience with their recovery using The Back2Play App, ask about any other interventions they had and if they have experienced a repeat injury during the time in the study.
- Delete the App from their phone during this interview and arrange to return (by scheduled pick up or FedEx label sent by The Research Assistant) device(s).
- 3 months following study enrollment, participants will be sent a survey through REDCap about reinjury to complete.

Participants who have been randomized to the usual care group will be asked to:

- Receive the usual course of care given by the hospital, General Practitioner or clinic which may or may not include written guidelines, suggestions or resources
- Complete the initial post-concussive symptom survey with The Research Assistant.
- Complete symptom surveys and daily surveys about cognitive and physical activities as well as self-rating of participants' own cognitive level of activity and stage of concussion recovery every 24 hours emailed by REDCap until 2 days following symptom resolution.
- Participate in a Zoom visit 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 Usual Care guidelines they received and about any other interventions they may have received. 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 survey about reinjury.

8. DESIGN

Phase 3 of this study has both quantitative and qualitative components. The aims of the qualitative components of the study are to determine if participants liked using The App, and if their experiences of using it helped their recovery from concussion. In addition, qualitative data will be used to review any improvement suggestions to The App before commercialization. Using both qualitative and quantitative research methods we will explore

the usability of The Back2Play App components under consideration for the final version of the App to be commercialized.

Primary Research Outcomes

To assess:

- Risk for repeat head injuries within three months of study completion (3-6 months after injury)
- Duration of symptoms: Time to symptom resolution from date of injury

Secondary Research Outcomes

To assess:

1) The frequency of symptoms using PCSS.
2) Time to return to activity and time to progress through the 6 stages of RTA
3) Perceptions of the platform by parents and youth.
4) Accuracy of the algorithm embedded in the background of The App classifying the participant's stage of recovery

Measures

Symptoms

Concussion symptoms will be assessed on The Back2Play App for those randomized to The App group and via REDCap for those randomized to Usual Care. A modified version of the PCSS (consisting of 22 symptoms) will be completed by youth in both groups. The Likert scale was modified to detect the presence of symptoms rather than symptom severity. Symptom data will be collected 3x/day for participants using The Back2Play App and every 24 hours for participants in the Usual Care group.

Cognitive Activity

Cognitive activity will be assessed using a modified version of the scale developed by Brown et al. Participants in both groups will be asked to complete this scale once per day through REDCAP which will appear as follows:

"Please rate 1-5 what you've been doing today"

1- None- No reading, homework, text messaging or screen time (T.V., cell phone), can talk on phone
2- Minimal- 15 minutes of screen time or schoolwork 2x daily. Socialize with 1-2 friends, no longer than 30 minutes,
3- Moderate- Homework in 15 minutes blocks for a maximum of 45 minutes. Screen time/T. V in 15-minute blocks, for up to an hour daily.
4- High- Complete as much homework as tolerated. 1 test/week or tests with accommodation (i.e. longer time to write), less reading, homework and screen time than normal
5- Full- no restrictions to cognitive activity

Cognitive and Physical Activities

Engagement in cognitive and physical activities will be measured once per day in those using the App as well as for those in the Usual Care group. The activities surveyed will match those recommended for each stage of RTA/RTS (Appendix 1.2)

Time to Stage
Participants in both groups will report their stage of RTA/RTS. The time from injury to each stage will be used to determine the time to stage and completion of the RTA/RTS guidelines.

Rate of Reinjury
All participants be asked at study completion and 3 months after symptom resolution if they have hit their head again in such a way that they experienced symptom exacerbation or return of symptoms for more than one day, if they moved back a stage in the guidelines for recovery, or if they sought medical care from hitting their head since the initial injury.

9. DETAILED DESCRIPTION OF METHODOLOGY

9.1. REIMBURSEMENT

Participants will be reimbursed for parking at all study locations (McMaster University) should they decide to attend the visits in person. Participants will be provided with an honorarium of $20 for their involvement in the study. If participants in The App group use their own phone, they may be provided up to $25 in compensation for data usage on their cellular device.

9.2. RISKS

Some participants may experience worsening of post-concussion symptoms during the completion of the study, due to physical or cognitive exertion (headache, dizziness, nausea etc.). In the event of worsening post-concussion symptoms, use of The Back2Play App will be immediately stopped and resumed only after a minimum period of 24 hours of rest and a resolution of symptoms. If participants do not want to continue with the testing, there will be no negative consequences. In addition, some participants may feel anxious about using The Back2Play App and their performance. The Research Team will explain the use of The Back2Play App in detail and will take special care to emphasize that results will be completely confidential and not shared with anyone outside of the Research Team.

9.3. BENEFITS

The potential benefits of carefully monitoring youth to control their activity level and better follow the protocols for restricted activity is that youth and their families will be better informed about their concussion symptoms and level of activity. Close monitoring will also alert the family, the youth, school and the Research Team of any concerning symptoms and need for intervention. Adhering to the RTS/RTA protocols may help prevent the youth from returning to activity before they are ready, and this can help to prevent further injury to a vulnerable recovering brain.

9.4. STUDY WITHDRAWAL

Participants can withdraw from this study at any time. They may contact the Principle Investigator/Research Coordinator to let them know they wish to no longer participate. Participants will be made aware that they can withdraw at any time and there will be no negative consequences. Immediately following study withdrawal, participants in The App group will be directed to unpair the watch from their personal phone if used and remove the App. Study equipment (phone, watch) will be returned by the participant either by provided Fedex postage or drop off at The McMaster Institute for Applied Health Sciences.

9.5. DATA ANALYSIS PLAN

The recordings of online consent (Zoom), for Phase 3, will be stored on a study computer and saved to a secure password encrypted server. As described above, participants will be asked to complete the (SUS). The SUS yields a single number representing a composite measure of the overall usability of the system being studied. Adjustments and modifications to The Back2Play App will be made before commercializing the product.

We will collect and report descriptively all demographic information, injury-related data (type, mechanism of injury, numbers of injuries), youth premorbid health history. Descriptive statistics such as means, medians, and frequencies will be reported where appropriate. Baseline comparisons will be performed between those that use The App and those whose recovery involved Usual Care with variables of mechanism of injury, age, sex, school performance and concussion history. These variables will be-analyzed using Pearson Chi Squared Cross Tabulations, T-Test and ANCOVA, to ensure the groups are similar. We will also evaluate agreement of the algorithm with the self-reported stage of recovery participants input using these same statistics.

The dichotomous variable, repeat injuries (coded as yes or no), will be analyzed using multivariate logistic regression and resulting odds ratios to determine if using The Back2Play App decreases risk of repeat injury. Confounders of age, gender, number of symptoms, time since last injury and comorbidities of premorbid mental health issues or learning disabilities will be examined as to their potential impact on outcomes. Many of these variables will be correlated with each other and these correlations will need to be examined carefully before they are entered into the analyses.

Time to symptom resolution will be analyzed using survival curves with Multivariate Cox regression analysis. Cox regression (also called proportional hazard models) is a method of survival analysis that models the time until some event as a function of either continuous or categorical predictors, allowing for the fact that not all subjects will experience the events of interest and that they will occur at different times.

9.6. DATA STORAGE AND SECURITY

Physical files are stored in the locked cabinets in CanChild (IAHS 408) with keys only held by 3 research staff. Computers for this project are located in CanChild. A username and password are required for access ~~on~~to the computers/network and study specific documents are further restricted to the study team. Access to all data would require a data log to be completed. The Secure Network belongs to McMaster University and stored in a tier 4 data facility. The data centre is physically located in Hamilton, ON. Hamilton Health Sciences and McMaster University provides physical building security employing a card access system. There is a Cisco ASA Firewall in place. The server is running Windows 2008 R2 version. Any data from surveys will be completed online, deidentified, and stored onto REDCAP (https://canchild.mcmaster.ca/). REDCap (Research Electronic Data Capture) is a secure web application for building and managing online surveys and databases (www.project-redcap.org). As in several Canadian pediatric academic centers, REDCap has been set up in CanChild Centre for Childhood Disability Research at McMaster University to support research. Data is stored on a secure, firewall protected server with regular backup in the Faculty of Health Sciences Computer Services Unit with only the https port available to the internet. Data can be entered by designated users or survey respondents from any computer with an internet connection. Data will be anonymized upon entry and stored for 10 years.
All data collected by The Back2Play App is stored locally on an anonymized relational database through McMaster's Research and High Performance Computing Service. The data will be analyzed within this database and downloaded to study computers by the research staff all in de-identified form. All Personal Health Information will be stored within a REDCAP form which will be separate from all participant devices and the App database. For example, the participant would not use their name as an identifier but would be given a code assigned by the research staff.

Devices loaned by CanChild have a password that is shared with the user to prevent easy access to the device if it is misplaced. Users who are given a study phone **and** watch do not need to use personal data as the devices are set up and paired using an apple id that is associated with the study, not the user. No personal information is collected by the watch or phone. When users pair their personal iPhone with a study Apple watch, personal data is shared between the devices (Health Kit, texts, pictures etc.). Users are instructed to unpair their phone from the watch prior to returning, thus erasing all personal data. If they forget and cannot be contacted to do this remotely the watch will be unlocked by Apple and the study team will unpair and reset the watch to factory settings.

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Appendix 1.1
Business Rules for In-App Notifications

<u>Progression through the CanChild RTA/RTS Guideline</u>

1. Participants cannot enter RTA Stage 4 until they have completed RTS Stage 1-3
    - If the participant reports RTA Stage 4 when they are in RTS Stage 1 or 2 they will receive the message "*Stage 1, 2 and 3 come before RTA Stage 4!"*

2. Participants must complete RTS Stage 5 (Full Return to School) before they can enter RTA Stage 4.

    If the participant reports RTA Stage 4 or 5 when they are in RTS Stage 3 through 5, they will receive the message "*You should complete RTS Stage 4-5* ***before*** *RTA Stage 4-6*".

3. Participants will be recommended to move to Stage 2 of RTS after 7 days
    - If the participant reports RTS Stage 1 for 7 days, they will receive the message "*You reported being in Stage 1 for 1 week, time to move to Stage 2!"*

4. Participants will be recommended to move to Stage 3 of RTS after 14 days
    - If the participant reports RTS Stage 2 for 14 days, they will receive the message "*You reported being in Stage 2 for 2 weeks, time to move to Stage 3!"*

5. Once in RTS Stage 3, participants cannot move back to Stage 2.
    - If the participant reports RTS Stage 3 and moves back to RTS Stage 2, they will receive the message "*Once your reach RTS Stage 3, you should not return to RTS Stage 2".*

6. Participants are recommended to complete RTA and RTS Stage 1-3 together.
    - If the participant reports RTA Stage 3 while in RTS Stage 1 or 2, they will receive the message *"Remember, RTS and RTA Stage 1 to 3 should go together!"*

7. Participants will be cautioned when they try and skip a stage
    - If the participant skips from RTS Stage 2 to RTS Stage 4, they will receive the message *"You forgot RTS Stage 3, we recommend you log this stage first!"*

8. Participants will be cautioned when they try to move back a stage.
    - If the participant moves back a Stage i.e., RTS Stage 5 to Stage 4, RTA 5 to Stage 4 they will receive the message "*Are you sure you want to move back a stage?"*

9. Participants cannot progress to a new stage of RTA/RTS if 2 or more symptoms *worsen*
    - If the participant reports that 2 or more symptoms worsen (from morning to evening survey), **and** the participant attempts to progress to a new stage, they will receive the message "*We recommend you do not progress to a new stage and inform a parent of your symptoms".*

10. Participants cannot progress to a new stage of RTA/RTS if their total number of symptoms increases by 2.
    - If the participant reports an increase in symptoms by 2 (from morning to evening survey) **and** the participant attempts to progress to a new stage, they will receive the message "*We recommend you do not progress to a new stage and inform a parent of your symptom".*

CanChild RTA/RTS Symptom Strata

11. Participants will be classified to Strata A (Symptom Free within 48 hours after Injury) if their initial symptoms disappear within 24 hours or after 24-48 hours a participant reports ≤ 2 symptoms.
    - If symptoms worsen, a participant can transition to Strata B.
    - If the participant reports that their symptoms disappear within 24 hours, they will receive the message "Take at least 24 hours for each Stage as you complete the guidelines".

12. Participants will be classified to Strata B (Symptom Free/Symptoms decreases within 1-4 weeks post injury) if the report > 2 initial symptoms at 50 hours and continue at > 2 for 1 week (168 hours) up to 4 weeks. If the child's symptoms decrease, but are still >2, the child should remain in stratum B.
    - Once a participant is in Strata B, they can never go to Strata A.
    - If a participant is in Strata B and progressing through Stages within 2 days, but symptoms are getting worse, the child should take longer to progress through the stages.
    - If ≥ 2 Symptoms for a month, move the participant to Strata C

- Recommendation: “Take at least 48 hours for each Stage as you complete the guidelines”.

13. Participants will be classified to Strata C (Symptomatic for more than 4 weeks) if they report ≥ 2 initial symptoms for ≥ 4 weeks, or if the participant has been in Strata B for 1 month.
    - Once a participant is in Strata C, they can never go to Strata A or B.
    - Recommendation: “Take at least 1 week for each Stage as you complete the guidelines”.

Increasing or Worsening Symptoms

14. Participants will be reminded to share their symptoms with their parents if their number of symptoms increases by 2
    - If the participant reports 2 or more symptoms new symptoms, they will receive the message “We recommend you inform a parent of your symptoms”.

15. Participants will be reminded to share their symptoms with their parents if 2 or more symptoms worsen.
    - If the participant reports 2 or more symptoms worsen, hey will receive the message “We recommend you inform a parent of your symptoms”.

16. Participants will be recommended to slow down if their number of symptoms increases by 2
    - If the participant reports >=2 symptoms are reported worse at all 3 surveys (3x in one day), they will receive the message “Slow down! Take a rest”.

17. Participants will be provided positive feedback if their number of symptoms increases by 2
    - If the participant reported >=2 Symptoms logged Better, they will receive the message “Symptoms got better, Great job!”

Activity Recommendations

18. Participants will be recommended to reduce their activity if they exceed the following cut points:
    - RTA Stage 1: 5 mins of light activity
    - RTA Stage 2: 60 mins of light activity
    - RTA Stage 3: 120 mins of moderate activity
    - RTA Stage 4: up to180 mins of vigorous activity
    - RTA Stage 5: Unlimited activity *No Contact
    - RTA Stage 6: Unlimited *Contact
    - Light activity < 40 steps per minute (Stage 1-2)
    - Moderate activity 40-93 steps per minute (Stage 3)
    - MVPA >= 94 steps per minute (Stage 4)
    - Vigorous (Stage 5-6) doesn’t need to be distinguished
        - If the participant exceeds activity recommendations for RTA Stage 1 to 4 and symptoms increase, they will receive the message “Slow down!”

- If the participant exceeds activity recommendations for RTA, they will receive the message "You did a lot of activity today!"
- If the participant meets activity recommendations for RTA Stage 1 to 4, they will receive the message "Great job today!"

19. Participants will be cautioned to reduce their activity if their heart rate exceeds 180 bpm
    - If a child exceeds 180 bpm, the Back2Play App sends a cautionary they will receive the message "You are doing too much!"
    - If the participant within Stage 1-3 and HR exceeds 180 bpm more than once within an hour, second notification is sent up to 3 notifications/day.

HR, bpm	Excepted	If exceeds, send Notifications
Resting	70-85	100
Peak	180	>180

Appendix 1.2
In-App Surveys

Morning Assessments	MidDay Assessments	Evening Assessments
Stage 1- First assessment		
Post-Concussion Symptom Scale (Modified for App and hereon called Initial Symptom Survey) "How are you feeling this morning? Are you experiencing…" 1. A headache: Y/N? 2. Nausea: Y/N? 3. Balance Problems: Y/N? 4. Dizziness: Y/N? 5. Fatigue: Y/N? 6. Drowsiness: Y/N? 7. Sensitivity to light: Y/N? 8. Sensitivity to noise: Y/N? 9. Irritability: Y/N? 10. Sadness: Y/N? 11. Nervousness: Y/N? 12. Feeling more emotional: Y/N? 13. Feeling Slowed down: Y/N? 14. Mentally foggy: Y/N?	Global: "How are you doing today?" question. If response is "Bad" present symptom survey. "Please select what cognitive activities you have been doing today" 1. Socialize with friends 2. Talk on the phone 3. Text friends 4. Watch a short video/T.V. 5. Rest in bed 6. Light Reading 7. Other	**Cognitive Scale:** "Please rate 1-5 what you've been doing today" 6- None- No reading, homework, text messaging or screen time (T.V., cell phone), can talk on phone 7- Minimal- 15 minutes of screen time or schoolwork 2x daily. Socialize with 1-2 friends, no longer than 30 minutes, 8- Moderate- Homework in 15 minutes blocks for a maximum of 45 minutes. Screen time/T. V in 15-minute blocks, for up to an hour daily. 9- High- Complete as much homework as tolerated. 1 test/week or tests with accommodation (i.e. longer time to write), less reading, homework and screen time than normal 10- Full- no restrictions to cognitive activity "Please select what physical activities you have done today"

15. Difficulty concentrating: Y/N? 16. Difficulty remembering: Y/N? 17. Visual problems: Y/N? 18. Confusion with directions/tasks: Y/N? 19. Move in a clumsy manner: Y/N? 20. Answer questions more slowly than usual: Y/N? 21. Neck pain: Y/N? 22. Trouble sleeping: Y/N? "What Stage of the RTS protocol are you in? Select: 1, 2, 3, 4, 5" "What Stage of the RTA protocol are you in? Select: 1, 2, 3, 4, 5"		1. Get up and dressed 2. Chores/Housework 3. Going for a walk outdoors 4. Other "**Daily Symptom survey**"

Stage Two		
Daily Symptom survey Page 1: Current symptoms - App generates what was reported yesterday - Global "How are you" question Page 2: New Symptoms	"Please select what cognitive activities you have been doing today" 1- School work 2- Computer time 3- Socialize with friends 4- Text/phone friends 5- Watch video or tv 6- Play a video game 7- Play a board game 8- Read a book 9- Puzzles 10- Other	"Please rate 1-5 what you've been doing today" **Cognitive Scale** "What Stage of the RTS protocol are you in? Select: 1, 2, 3, 4, 5" "What Stage of the RTA protocol are you in? Select: 1, 2, 3, 4, 5" "What physical activities did you do today?" 1. Brisk Walk 2. Swim 3. Stretch/Yoga 4. Play Catch 5. Walk around the mall/grocery store 6. Walk to the bus/car 7. Move around/clean your room 8. Other "**Daily Symptom survey**"
Stage Three		
Daily Symptom survey Page 1: Current symptoms - App generates what was reported yesterday	"Please select what cognitive activities you have been doing today" 1. School work	"Please rate 1-5 what you've been doing today" **Cognitive Scale** "What Stage of the RTS protocol are you in? Select: 1, 2, 3, 4, 5"

- Global "How are you" question Page 2: New Symptoms	2. Socialize with friends 3. Text/phone friends 4. Use iPhone Apps i.e. Snapchat 5. Play on the iPad 6. Watch T.V. 7. Watch a YouTube video 8. Watch a movie 9. Play video games 10. Play a board game 11. Read/Re-read a book 12. Listen to music 13. Puzzles 14. Other	"What Stage of the RTA protocol are you in? Select: 1, 2, 3, 4, 5" "What physical activities did you do today?" 1. Walk 2. Jog 3. Bike 4. Hike 5. Swim 6. Stretch/Yoga 7. Skate 8. Play Catch 9. Passing, shooting drills 10. Dribbling/Stickhandling 11. Other "**Daily Symptom survey**"
Daily Symptom survey Page 1: Current symptoms - App generates what was reported yesterday - Global "How are you" question Page 2: New Symptoms	"Please select what cognitive activities you have been doing today" 1. School work 2. Test/Quiz 3. Study 4. Socialize with friends 5. Text/phone friends 6. Use iPhone Apps i.e. Snapchat 7. Play on the iPad 8. Watch T.V. 9. Watch a YouTube video 10. Watch a movie 11. Play video games 12. Play a board game 13. Read/Re-read a book 14. Listen to music 15. Puzzles 16. Other	"Please rate 1-5 what you've been doing today" **Cognitive Scale** "What Stage of the RTS protocol are you in? Select: 1, 2, 3, 4, 5" "What Stage of the RTA protocol are you in? Select: 1, 2, 3, 4, 5" "What physical activities did you do today?" 1. Jog 2. Bike 3. Hike 4. Swim 5. Stretch/Yoga 6. Skate 7. Play Catch 8. Passing, shooting drills 9. Dribbling/Stickhandling 10. Throwing/Passing drills 11. Sports-specific drills 12. Basketball 13. Soccer 14. Football 15. Hockey 16. Rugby 17. Resistance training 18. Track and Field 19. Squash/Tennis 20. Other "**Daily Symptom survey**"
Stage Five		

Daily Symptom survey Page 1: Current symptoms - App generates what was reported yesterday - Global "How are you" question Page 2: New Symptoms	"Please select what cognitive activities you have been doing today" 1. School work 2. Test/Quiz 3. Study 4. Socialize with friends 5. Text/phone friends 6. Use iPhone Apps i.e. Snapchat 7. Play on the iPad 8. Watch T.V. 9. Watch YouTube videos 10. Watch a movie 11. Play video games 12. Play a board game 13. Read/Re-read a book 14. Listen to music 15. Puzzles 16. Other	"Please rate 1-5 what you've been doing today" **Cognitive Scale** "What Stage of the RTS protocol are you in? Select: 1, 2, 3, 4, 5" "What Stage of the RTA protocol are you in? Select: 1, 2, 3, 4, 5" "What physical activities did you do today?" 1. Run 2. Jog 3. Bike 4. Hike 5. Swim 6. Stretch/Yoga 7. Skate 8. Play Catch 9. Jumping jacks/Burpees 10. Passing, shooting drills 11. Dribbling/Stickhandling 12. Throwing/Passing drills 13. Sports-specific drills 14. Basketball 15. Soccer 16. Football 17. Hockey 18. Rugby 19. Resistance training 20. Track and Field 21. Squash/Tennis 22. Other "**Daily Symptom survey**"

Appendix 1.3
Back2Play App Visuals

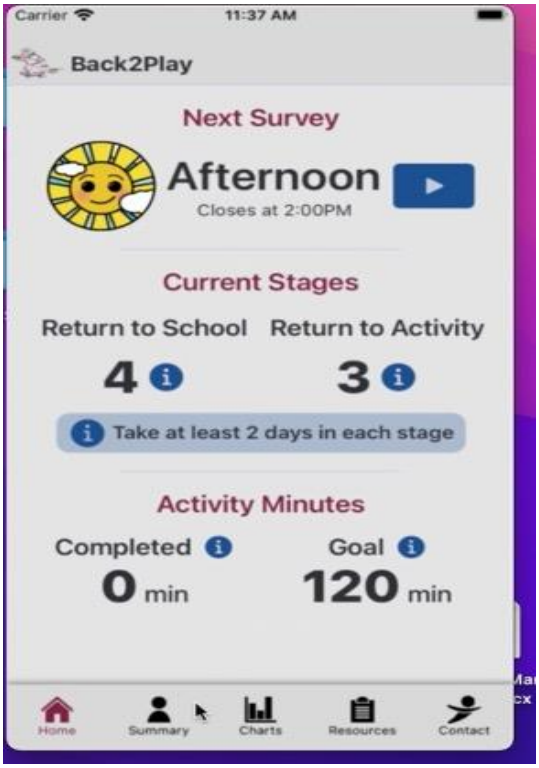


Figure 1. App Home

Figure 2. Pop-Up Email

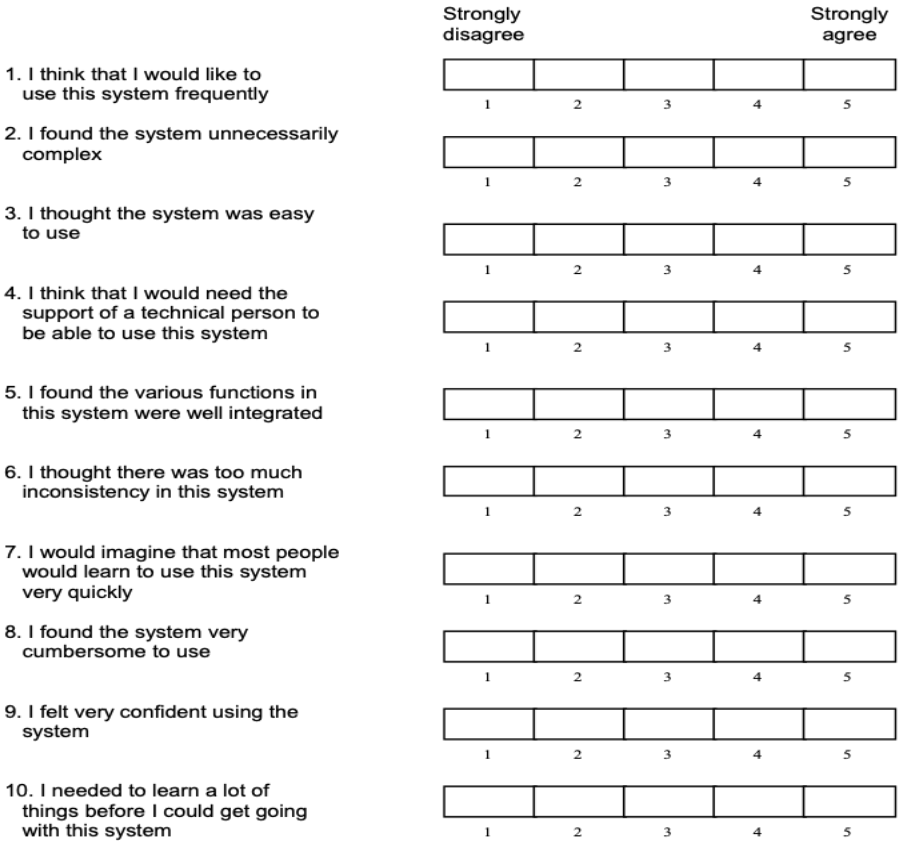
Figure 3. Charts Page

Appendix 1.4
Contact form

Consent to Contact: Participant Name/Age	Parent/Guardian- Name & relationship	Program or Setting obtaining consent to contact/Staff name	Notes

Appendix 1.5
System Usability Scale (SUS)

System Usability Scale



Appendix 1.6

Follow Up Interview

Ask Everyone:

Tell me about where you are in recovery from your concussion.

Prompts:

Are you still experiencing any symptoms?

Did you hit your head again during your recovery?

If yes did it increase symptoms and how did it affect your recovery?

Are you back fully to school and sport?

Do you feel back to your previous self?

Are there any other therapies or treatments that you tried during your recovery from concussion?

Prompts:

Medications, physio, chiro, other medical professionals

Ask App users:

Tell me about your experience in using the App during your recovery from concussion.

Follow Up questions:

Did you receive notifications from the App-give me some examples

Did you do the surveys on your watch or phone?

Did you ever use data or mostly Wi-Fi?

Did you ever forget to charge the watch? How often?

Did you agree with the guidance you were given re: activity or stage levels? (%)

Did you find the App helpful at all in your recovery-how so?

Did you like the App?

Follow up questions:

What were the best features of the App

Were there features you didn't use that much

Were there things that you didn't like or found annoying

How could we make it better?

Ask Usual care group

What was involved in your care and follow up with your concussion?

Were you given some sort of guidelines to follow to return to play and school?

What format were they in?

Did you seek extra treatment or help?

Did you feel you understood how to get better and get back to activities and school after your concussion?