PARENTAL CONSENT FOR CHILD TO PARTICIPATE IN RESEARCH (A)

TITLE	**SMART Concussion Trial** Symptom Management vs Alternative Randomized Treatment of Concussion	
SPONSOR	University of Calgary	
FUNDER	Canadian Institutes of Health Research (CIHR)	
PRINICPAL INVESTIGATORS	Dr Carolyn Emery Dr Keith Yeates	403.220.4608 403.220.2928
Research Coordinator/Nurse	Heather Godfrey 403.955.2797	

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your child's participation will involve. If you would like more detail about something described here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form for your records.

BACKGROUND

Concussion rates are rising in youth 13-19 years old and some of these adolescents will report symptoms for months following their injury. Many studies examine youth concussion, but few studies evaluate concussion *treatments*. Research evaluating the effectiveness of concussion treatments early after injury is very important. Your child has been identified as a possible participant in this study because they are 13-19 years old and have had a concussion in the past 2 weeks. Participation in this research study is voluntary.

STUDY PURPOSE

The purpose of this research study is to determine which concussion treatments are the most effective for relieving symptoms in adolescents 13-19 years old who have recently had a concussion. The results from this study will help us to determine which concussions treatments are most effective for specific symptom presentations following concussion.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 300 adolescents in Calgary will take part in this study through the Acute Sport Concussion Clinic. Participants may be approached in the emergency department at the Alberta Children's Hospital, may see posters in other clinics, or may self-refer into the Acute Sport Concussion Clinic.

WHAT WILL HAPPEN IF MY CHILD TAKES PART IN THIS STUDY?

First visit

If you agree to allow your child to participate in this study, we would ask them the following:
Your child will complete surveys about how they're feeling which may take up to 15 minutes. They will perform an exercise test on a treadmill to determine their personal exercise prescription. We will check your child's blood pressure and monitor their heart rate during the treadmill session. Participants will then receive concussion and exercise education. This portion of the study will be completed today and will take roughly 45 minutes. Following the treadmill test, your child will be assigned to 1 of 3 possible treatment arms based on the symptoms they have reported. We currently do not know which type of treatment is most effective for adolescents soon after concussion. The treatments we are studying are evidence based and

routinely used to treat a range of possible symptoms adolescents may develop following concussion. More detailed information about your child's specific treatment will be provided after randomization. We will collect a second consent form after you have a chance to review the information. The study schedule for all participants is as follows:

Study Schedule

	Consent & 1st Visit	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6	3 month F/U
Sports Medicine Doctor Visit	X		X	X	X	X	X	
Treatment		X	X	X	X	X	X	
Mobile Surveys	X				X (or at clearance)			X
Actigraph		X			X			
Treadmill Test	X				X (or at clearance)			

Treatment Sessions

Your child will be assessed by the study doctor 6 times and will receive 6 concussion treatments. Often these visits will occur together. Some visits may take place virtually. Treatment sessions will last between 15 minutes and 1 hour, depending on the treatment. The first treatment session needs to be scheduled within 3 weeks from the concussion date. All participants will be asked to wear an Actigraph for the 1st and 4th weeks of treatment. This is a small device your child will wear around their waist during the day and on their wrist at night while sleeping, to record their physical activity. Below is an example of the Actigraph that is worn on the wrist or around the waist.

Treatment Session 1

The first treatment will include a series of assessments specific to your child's symptoms. This will need to be an in-person visit. Your child will see the study doctor and will complete their first treatment. (There may be an option for your child to complete the first treatment today if the study team can accommodate). The Actigraph will be worn for one week following this session.

Treatment Session 2

Your child will be seen by the study doctor and have their 2nd treatment session.

Treatment Session 3

Your child will be seen by the study doctor and have their 3rd treatment session.

Treatment Session 4

Your child will see the study doctor and have their 4th treatment session. This visit will have to occur in person. If your child is cleared to return to full activity by the doctor, they will repeat the assessments from treatment 1, complete the symptom surveys, and have another treadmill test, today. (These occur following the session your child is cleared to return). The Actigraph will be worn for one week following this session.

Treatment Session 5

Your child will be seen by the study doctor and have their 5th treatment session.

Treatment Session 6

This session your child will see the study doctor and have their 6th treatment session. If still experiencing symptoms, the study doctor will continue to see your child.

3-month follow-up

At the 3-month follow-up, your child will complete the same surveys, again from a mobile device. If still experiencing concussion symptoms, your child can see the study doctor again and plan for further treatment.

HOW LONG WILL MY CHILD BE IN THE STUDY?

- Your child will be in this study for 6 weeks of treatment plus the electronic surveys at 3 months
- There will be a total of 6 treatments and 6 physician visits over 6 weeks
- Participation will require ~2 hours today, ~ 1 ½ hours for treatment session 1, and ~1 hour for sessions 2-6. The 3 month surveys will take 15-20 minutes

WHAT WILL HAPPEN WHEN MY CHILD IS FINISHED THE STUDY?

Based on recent data on how quickly adolescents recover from concussion, most participants will be fully recovered by the end of the study. If your child is still having symptoms from your concussion following the last treatment session, the study doctor will continue to see and treat your symptoms.

ARE THERE ANY POTENTIAL RISKS OR DISCOMFORTS THAT MY CHILD CAN EXPECT FROM THIS STUDY?

Your child's safety is very important. This study poses minimal risks to participants. The treatments and tests in this study could temporarily worsen your child's concussion symptoms, like any concussion treatment your child might receive in the community. Symptoms, like worse headache or dizziness, should only increase for a short time and resolve quickly. Exercise testing and the recommended physical activity may produce an increase in symptoms that should also go away quickly. All physical assessments will be done under close supervision and every effort will be made to ensure your child's safety. The risk of injury will be reduced by careful supervision by trained research team members during testing procedures. Your child will have the opportunity to consult the study physician, just like normal care, at any point during the study. We will watch for any 'red flag symptoms' like double vision or vomiting and in that case would send your child to a local emergency department. The minor risks associated with this study are comparable to the risks of seeking treatment on your own in the community. Your child will remain under the care of a study sport medicine physician throughout the study.

ARE THERE ANY POTENTIAL BENEFITS IF MY CHILD PARTICIPATES?

We will thoroughly assess your child's concussion symptoms and the treatments may improve symptoms more quickly than without treatment. This study will help researchers understand more about which treatments work more effectively for certain concussion symptoms in 13-19 year olds. Hopefully, this information will help other adolescents like your child receive the best treatment for concussion in the future. There may be no benefit from participation in this study.

WHAT OTHER CHOICES DO WE HAVE IF MY CHILD CHOOSES NOT TO PARTICIPATE?

If your child chooses not to participate, your child will receive the usual standard of care from your medical team. Participation is completely voluntary and if you decide against your child taking part in this study, there will be no penalty to them or to you. Your decision will not affect the standard medical care your child receives.

CAN MY CHILD STOP BEING IN THE STUDY?

Yes. You can decide to stop your child's participation at any time. Tell the study doctor if you or your child are thinking about stopping or decide to stop. The doctor will discuss what follow-up care and testing could be most helpful.

CAN THE RESEARCHERS REMOVE MY CHILD FROM THIS STUDY?

The researchers may end your child's participation in this study for multiple reasons, such as if your child's safety and welfare are at risk, or if your child does not follow instructions or misses scheduled visits. The researchers may also decide to stop the study at any time. If your child decides to stop being in the study or cannot continue, the study team may still ask your child to complete the symptom surveys.

WITHDRAWAL OF STUDY DATA

If your child decides to stop being in the study or is removed from the study, or the study is stopped, your child can choose to withdraw their study data at any time up until the last study visit. If your child does not complete the study and would like their data withdrawn, please email the study team and your child's data up to that point will be deleted. Once your child has completed the study, their data cannot be removed. University policy requires that we keep your research records for at least five years after final publication of the study results.

WILL MY CHILD BE PAID FOR PARTICIPATING, OR DO WE HAVE TO PAY FOR ANYTHING?

You will be reimbursed for parking during study visits at the Acute Sport Concussion Centre at the University of Calgary Sports Medicine Centre. Your child will not be paid directly for their participation in this research but will receive a $50 gift card once they've completed their 6 treatments and surveys as a small gift to recognize their participation.

WILL INFORMATION ABOUT MY CHILD AND THEIR PARTICIPATION BE KEPT CONFIDENTIAL?

All information about your child will be kept as confidential (private) as possible, unless required by law. There is always the potential for an unintended breach of privacy. The research team will handle data according to the Data Management Plan as outlined below:

- Symptom surveys that your child completes using their mobile device and assessment information the study team collects from them, will be stored using REDCap. REDCap is a secure, online electronic data capture platform that requires double verification for study team members to sign in. The information provided by internet survey will be matched only to a study ID, not to your child's personal identifiers
- Your child's personal info (name, date of birth, contact information) will be kept within a separate arm of the REDCap study server. The server has 2 factor identification and is only accessible by the study team
- Research data and records on paper will be maintained in a secure location (locked filing cabinet) in the Faculty of Kinesiology, 3300B, University of Calgary. Only authorized individuals will have access to it
- Your child will not be identified by name in any publication of the research results and all analysis/results will be presented as group data

If your child participates, their information related to this research will be made available as needed to regulatory authorities, including the University of Calgary Conjoint Health Research Ethics Board. This organization will treat such information with strict confidentially. This means that no records bearing your child's name will be provided to anyone with exception of the regulatory authorities, where necessary, and investigators involved in this study.
By signing this form, you are authorizing such access. If you decide to revoke this consent at any time, please notify Dr Carolyn Emery or Dr Keith Yeates in writing.

IF MY CHILD SUFFERS A RESEARCH-RELATED INJURY, WILL THEY BE COMPENSATED?

It is important that you tell the researchers if you believe that your child has been injured because of taking part in this study. If your child suffers injury because of participating in this research, no compensation will be provided by the

University of Calgary or the researchers. However, your child still has all their legal rights. Nothing said in this consent form alters your child's right to seek damages.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The Research Team: You may contact Heather Godfrey (Research Coordinator and Nurse) at 403.955.2797 or Heather.Godfrey@ahs.ca with any questions or concerns about the research or your participation in this study.

Conjoint Health Research Ethics Board (CHREB): If you have any questions concerning your child's rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403.220.7990.

Public Information about this Study: ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial is available on www.ClinicalTrials.gov. This website will not include information that can identify study participants. At most, the website will include a summary of the results. You can search this website at any time.

HOW CAN MY CHILD FIND OUT ABOUT THE STUDY RESULTS?

Participants in this study will be able to access the results of the study once they are analyzed and published in a journal or on the website listed above. You may email the study team after your participation is complete to inquire when results will be published.

WHAT ARE MY CHILDS RIGHTS IF THEY TAKE PART IN THIS STUDY?

Taking part in this study is you and your child's choice. Your child can choose whether they want to participate. Whatever decision your child makes, there will be no penalty to you or your child.

- You and your child have a right to have all questions answered before deciding whether to take part
- You and your child's decision will not affect the standard medical care they receive
- If your child decides to take part, they may leave the study at any time

WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT MY CHILD?

During the study, the researchers could learn something about your child that they didn't expect. For example, the researchers may find out your child has another medical condition. The study doctor will consult with other medical experts as needed to evaluate the findings and will then share these results with you. You will be helped with arranging appropriate follow up and care.

I consent for the researchers to share findings with me:

- ❑ YES
- ❑ NO

HOW LONG WILL INFORMATION FROM THE STUDY BE KEPT?

The researchers intend to keep the research data and records until the research is published and/or presented, or approximately 5 years. Data may also be shared at later dates with other researchers for future studies that are unknown at this time. Any data shared with other researchers, will not include your child's name or other personal identifying information. Any future use of this research data is required to undergo review by a Research Ethics Board. My child's data may be kept for use in future research to learn about, prevent, or treat other health-related problems.

- ❑ YES
- ❑ NO

CONTACT FOR FUTURE RESEARCH

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University of Calgary researchers may contact my child in the future to ask them to take part in other research studies.

- ❑ YES
- ❑ NO

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

Your signature on this form indicates that you have understood to your satisfaction the information about your child's participation in the research project and your child agrees to participate. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities.

_____

Name of Participant

SIGNATURE OF PARENT OR LEGAL GUARDIAN

_____	_____	_____
Name of Parent or Legal Guardian	Signature of Parent or Legal Guardian	Date

SIGNATURE OF PERSON OBTAINING CONSENT

_____	_____
Name of Person Obtaining Consent	Contact Number
_____	_____
Signature of Person Obtaining Consent	Date

SIGNATURE OF THE WITNESS

_____	_____	_____
Name of Witness	Signature of Witness	Date

A signed copy of this consent form will been given to you to keep for your records and reference.