Study Name: Web-Based Self-Monitoring Activity-Restriction and Relaxation Training Program for Kids With Mild Traumatic Brain Injury

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STUDY TITLE: Kids with mTBI Get SMART: Development and Pilot Trial of a Web-Based, Self-Monitoring Activity-restriction and Relaxation Training (SMART) Program (Phase 2)

SPONSOR NAME: National Institutes of Health/Eunice Kennedy Shriver National Institute of Child Health and Human Development

SPONSOR STUDY NUMBER: R21HD087844

INVESTIGATOR INFORMATION:

Lynn Babcock, MD and Shari Wade, Ph.D.	513-803-2956
Principal Investigator Name	24 hr Emergency Contact

INTRODUCTION:

Throughout this document, references to "You" refer to the patient study participant. If the participant is under 18 years of age or otherwise unable to legally give informed consent to participate in this research study, the parent(s) or legal guardians will provide parental permission. The signature(s) at the end will clarify whether the research participant is signing this consent form on their own behalf or via a legal guardian.

We are asking you to be in a research study so that we can learn new information that may help others. Participation in this study is totally **voluntary**. If you decide not to be in this study, we will still take good care of you. If you decide to be in this study, you may change your mind at any time during the study and you can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to be in the study.

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WHY ARE WE DOING THIS RESEARCH?

The purpose of this research study is to find out whether an internet based computer program (called SMART) is helpful to patients who are recovering from a head injury, also known as a concussion.

WHO IS IN CHARGE OF THIS RESEARCH?

This study is directed by **Dr. Lynn Babcock** and **Dr. Shari Wade**, both researchers at Cincinnati Children's Hospital Medical Center (CCHMC).

CCHMC is being paid by National Institutes of Health/Eunice Kennedy Shriver National Institute of Child Health and Human Development to conduct this study.

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You have been asked to take part in this research study because you are 11-18 years old and within the 2 last weeks, you suffered a head injury involving at least one of the following symptoms:

- Temporary confusion or disorientation around the time of the injury
- Loss of consciousness, but it lasted less than 30 minutes
- Memory problems from around the time of injury
- A seizure around the time of the injury
- Headache, dizziness, feeling irritable, trouble concentrating, or feeling very tired following the injury.

WHO SHOULD NOT BE IN THE RESEARCH STUDY?

You should not be in the study if you are unable or unwilling to provide consent or participate in the study. Additionally, you should not be in the study if any of the following applies:

- You or your parent/guardian do not speak or read English
- You do not have internet access
- Your head injury was severe enough to require hospitalization
- Your symptoms were due to drinking alcohol or taking drugs or medications that may make you confused
- You have other medical problems that may reduce your ability to participate in the study.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

You will be in the research study for about four weeks.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

Up to 100 patients and their parents/guardians will be recruited to participate.

WHAT WILL HAPPEN IN THE RESEARCH STUDY?

If you agree to participate in this study, you will be randomized to one of two groups. One group will receive the SMART program along with usual concussion care. The other group will receive usual concussion care with no access to the SMART program. You will be put into a study group by chance, like flipping a coin. You will have an equal chance of being in either study group.

All Participants in Both Groups Will Complete the Following Study Procedures
You and your parent/guardian will both fill out some questionnaires during your visit today. These will include questions about your health and symptoms before and since your head injury. They will also include questions about your general behaviors and feelings and any recent medical care. These surveys will take about 30 minutes to complete.

You and your parent/guardian will then be asked to continue filling out the same questionnaires weekly for four weeks. You will also be asked to report any medical visits for concussion and any resources you use to find information about concussion.

If you visit a health care provider for your concussion, you will be asked to give us contact information for the provider you saw, so that they can be sent a brief questionnaire. We will not contact any providers or practices who you do not name in your questionnaire responses, and we will not share any information about your survey responses or information you enter into the SMART program with your health care providers.

Participants Assigned to the SMART Group will Complete These Additional Procedures
If assigned to receive the SMART program, a member of the study team will introduce you to the program and show you how to log in during your visit today. During the next four weeks, you will be asked to log in to the program daily. You will be able to view modules and complete activities to learn

more about concussion recovery. You will also be asked to enter information about your symptoms and activities daily, and will be able to access a weekly report that shows how your recovery is going. You can use this for your own reference or show the report to your health care provider if you have an appointment for your concussion.

When you are using SMART, the program will track how you move through the program and how long you spend in different sections. We are collecting this information to help us learn more about how people use SMART, and to help us see how easy or hard it is to use.

WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

Being in this study may not help you right now. When we finish the study, we hope that we will know more about how an online program can help patients recovering from concussions. This may help other patients with concussions later on.

WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

There is a risk of breach of confidentiality related to the study. However, this risk will be minimized by giving all participants an identifying study number for coding and analyzing data related to the study. Additionally, data will be stored on a locked database that only members of the study team will be given access to.

There may also be a slight risk that interacting with the SMART system or the weekly surveys could temporarily make concussion symptoms worse. However, the system has been designed to minimize this risk, and other research studies have shown that computerized testing after a concussion usually does not increase symptoms. If at any time you have worries about your concussion symptoms, the doctors conducting this research can make arrangements to have you meet with a physician in the Concussion Clinic.

There may be other risks that we do not know about yet.

WHAT OTHER CHOICES ARE THERE?

Instead of being in this research study you may choose not to participate.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?

Making sure that information about you remains private is important to us. To protect your privacy in this research study, we will take the following steps: All study participants will be given a unique study number which includes no personal identifying information, study forms will be kept in a locked cabinet, and all computer data forms will be password protected. A copy of this consent form will be included in your medical research record.

By signing this consent form you are giving permission for representatives of the Cincinnati Children's Hospital Medical Center (CCHMC), the Investigator and CCHMC employees involved with the research study including the Institutional Review Board and the Office for Research Compliance, to be allowed to inspect sections of your medical and research records related to this study.

In unusual cases, the investigators may be required to release personal identifiable information (which may include your personal identifiable medical information) related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Ohio law, the appropriate agencies. There is a legal obligation for investigators to report child maltreatment or child abuse to the appropriate agency.

The information from the research study may be published; however, your personal identifying information will not be reported in such publication. The publication will not contain information about you and your child that would enable someone to determine your identity as a research participant without your authorization.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the study results. You can search this website at any time.

Because this research study involves payment for participation we are required by federal Internal Revenue Service (IRS) rules to collect and use your social security or tax ID number (SSN) in order to track the amount of money that we pay you. Unless you have given specific permission for another use of your SSN related to this research we will only use your SSN to keep track of how much money we pay you and your SSN will not be used as part of this research.

WHAT IF NEW INFORMATION BECOMES AVAILABLE DURING THE RESEARCH?

The study doctor will tell you if they find out about new information from this or other studies that may affect your health, safety, or willingness to stay in this study.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

You or your insurance company will be responsible for the costs of your medical care. You will not be charged extra for participation in this research study.

As part of the study, you may receive email/mail/text messages reminders to complete surveys for about 1 month. Depending on your cellular phone service, this could result in charges to your cellular phone bill. Please indicate here whether or not you choose to use texting for this study.

_____ I consent to receiving and sending text messages for the study purposes. I understand that I may be charged for this on my cellular telephone bill.

_____ I refuse to receive and send text messages for the study purposes.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

You will be reimbursed for your time and effort while you are in this research study. Reimbursement for participating will be paid on the following schedule based on completing all required questionnaires within 2 days of the due date:

$10 for completing initial baseline assessments
$15 for completing the 1-week follow-up questionnaires
$20 for completing the 2-week follow-up questionnaires
$25 for completing the 3-week follow-up questionnaires
$30 for completing the 4-week follow-up questionnaires

Participants may receive up to $100 for completing all study procedures. We will give you your payment in the form of a reloadable debit card (ClinCard) and you will receive a handout that will explain how to use the card. We will provide you with a card and we will load money onto your card after each set of follow-up surveys is completed, based on the schedule listed above. Incentives will be mailed and/or provided in person during a visit to CCHMC or at your home. A W-9 form may need to be completed by you in order to receive the incentive.

WHAT HAPPENS IF YOU ARE INJURED FROM BEING IN THIS STUDY?

If you believe that you have been injured as a result of this research you should contact Dr. Lynn Babcock at 513-803-2956 as soon as possible to discuss the concerns. Treatment for injuries is available at CCHMC. If you or your child go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in a research study. If possible, you should give them a copy of this consent form.

CCHMC follows a policy of making all decisions about compensation for the medical treatment of physical injuries that happened during or were caused by research on an individual basis.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions, concerns, or complaints about this research study you can contact the study person listed on page 1 of this document or Lead Coordinator, Noura Barazi at 513-808-1494.

If you would like to talk to someone that is not part of the research staff or if you have general questions about your research study rights or questions, concerns, or complaints about the research, you can call the CCHMC Institutional Review Board at 513-636-8039.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?
CCHMC will need to use and share your PHI as part of this study. This PHI will come from:
- Your CCHMC medical records
- Your research records

The types of information that will be used and shared from these records include:
- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

Who will share, receive and/or use your protected health information in this study?
- Staff at all the research study sites (including CCHMC)
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the CCHMC Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your PHI is not misused?
People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?
You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?
Your permission will expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

Will your other medical care be impacted?
By signing this document you are agree to participate in this research study and give permission to CCHMC to use and share your PHI for the purpose of this research study. If you refuse to sign this document you will not be able to participate in the study. However, your rights concerning treatment <u>not</u> related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

SIGNATURES:

I have read the information given above. The investigator or his/her designee have personally discussed with me the research study and have answered my questions. I am aware that, like in any research, the investigators cannot always predict what may happen or possibly go wrong. I have been given sufficient time to consider if I should participate in this study. I hereby give my consent to take part in this study as a research study subject. I will receive a copy of this signed form for my records.

Printed Name of Research Participant	Date
Signature of Research Participant Indicating Assent or Consent	Date
Signature of Parent or Legally Authorized Representative* Indicating Permission for Patient <18 years old to Participate	Date

* If signed by a legally authorized representative, a description of such representative's authority must be provided.

Signature of Person Obtaining Consent	Date