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# Kids with mTBI Get SMART: Refinement and Pilot Trial of a Web-Based, Self-Monitoring Activity-restriction and Relaxation Training (SMART) Program

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## Introduction

Mild traumatic brain injury (mTBI) is the one of the most common injuries sustained by youth in the US.[1-3] Following the acute injury, over half of these youth will incur physical, cognitive, emotional, and/or sleep-related dysfunction commonly referred to as post-concussion syndrome (PCS).[4-7] Effective treatments targeted at reducing the impairment would have a significant public health impact; however, for youth there are only 3 published mTBI treatment trials to date.[8-11] A report to the Congress on mTBI published by the CDC[12] and proceedings from the WHO Collaborating Centre Task Force on mTBI[9] highlighted this lack of evidence-based treatment strategies and called for more trials investigating treatments. mTBI is an acute event with heavy initial symptom load which is managed primarily in outpatient settings. An innovative web-based therapy may be the ideal mode of intervention delivery since it can be easily and frequently accessed without an outpatient visit. Research by Co-I Wade involving youth with complicated mild to severe TBI has demonstrated the feasibility of web-based therapy with this population, as well as its efficacy in restoration of executive function and improvement of behavioral symptoms relative to access to web-based education alone.[13-19]

To address this critical public health need for accessible, evidence-based treatments for mTBI, our objective was to develop and pilot an interactive individualized web-based intervention program for youth with mTBI and their families — the Self-Monitoring Activity-Restriction and Relaxation Treatment (SMART) program — to ultimately reduce the functional impairment that follows the injury. SMART incorporates real-time recommendations for individualized symptom management and activity restrictions tied to current PCS symptoms, as well as anticipatory guidance, and training in evidence-based stress management, relaxation, problem-solving skills, and cognitive behavioral therapy. Acquisition of critical data about the feasibility and efficacy of this intervention from this proposal has paved the path for an externally fundable proposal to conduct a larger, randomized clinical trial (RCT) for youth with mTBI. This will be amongst the first of its kind. Our objective of this protocol was conducted in two phases and we had the following **specific aims**:

**Aim 1: Refine SMART a web-based intervention providing real-time individualized symptom management and cognitive-behavioral skills, for youth ages 11 to 18 years with mTBI**.
*Outcomes:* Using stakeholder feedback and usability data, we refined a program that is acceptable, comprehensible and relevant for youth with mTBI and their families.
*Hypothesis 1-1*: Youth and parent evaluations of the usability of the SMART modules, as assessed by the System Usability Scale, will be adequate (> 68 of 100).
A**im 2: Evaluate the feasibility and preliminary efficacy of the SMART program (from Specific Aim 1) through an open test pilot with up to 35 youth ages 11 to 18 years who present to the ED with mTBI.**
*Outcomes:* In this first trial of SMART, we acquired critical data that demonstrated the feasibility of administering SMART and to inform further modifications of the program for a future randomized clinical trial.
*Hypothesis 2-1*: Youth and their families receiving SMART will rate the intervention as acceptable, easy to use, and helpful. Youth and parent evaluations of the usability of the SMART modules, as assessed by the System Usability Scale, will be adequate (> 68 of 100).
*Hypothesis 2-2*: Youth and their families will demonstrate adequate adherence to the program and will report a reduction in post-concussion symptoms and stress related to the mTBI.

## Executive summary

Given the high incidence of concussions and morbidity that follows the injury; there is a critical need for an evidence based treatment program for children with concussion. Overall, we developed an innovative, cost-effective, and acceptable program aimed at decreasing the morbidity for children who sustain concussions. Our preliminary evidence suggests that this program is useful and acceptable. We also showed that participants of the program experience symptom improvement during engagement with the program. Our participants expressed a positive experience with the study. One mother commented that the program provided "what I think every parent would need to know about brain injuries."

We believe that the program is a thorough resource for parents and patients. We see this program being used to supplement discharge instructions and follow-up care. Additionally, we anticipate that the real-time symptom and activity tracking and feedback will help guide the decisions parents and patients make related to returning to school and activities. Our hope is to change our patient's outcome by reducing their recovery time through personalized comprehensive instruction and feedback that takes the guesswork out of effectively managing symptoms and safely returning to school and activities.

We plan to continue to refine our program and gather additional evidence about its effectiveness. Once we have achieved those goals, we plan to disseminate our program to providers who care for children with mTBI, regionally within Ohio and within the nation.

## Information / qualifications – principal and all co-investigators

We had a skilled and accomplished interdisciplinary research team that worked together to achieve our stated goals. The main investigators include:

1. Dr. Babcock, Principal Investigator from the Division of Emergency Medicine, whose research has been focused on mTBI has piloted the web-based assessments in the ED. She developed the procedures for recruitment, enrollment, and assessment that will ensure the success of the proposed methodology. She assisted with the refinement of the modules, study conduct, and data analysis.
2. Dr. Wade, Co-investigator from the Division of Physical Medicine and Rehabilitation, is an international leader in developing interventions for pediatric TBI and a pioneer in web-based approaches. With her extensive experience, she assisted with every aspect of the project and helped to problem solve issues as they arouse.
3. Dr. Brad Kurowski, Co-investigator from the Division of Physical Medicine and Rehabilitation, had the research expertise on physiological and environmental factors that influence the course of recovery following TBI. He helped to refine the modules for the program as well as develop the logic for the program.
4. Dr. Judith Dexheimer, Co-investigator from Divisions of Emergency Medicine and Biomedical Informatics had the essential experience needed to develop the logic for programs detailed in this project. In addition, she was a liaison with Biomedical Informatics ensuring adherence to timelines and clarification of issues.

## A review of the literature related to the project topic

Traumatic brain injuries are the leading cause of death and disability for Ohio children. Within Ohio, over 25,000 children 18 years of age and younger are evaluated in ED annually, and this number is increasing each year.[1] About 75-85% of these injuries are referred to as "mild" traumatic brain injuries (mTBIs) or concussions.[2] mTBI involves a complex pathophysiological process following traumatic

forces to the head that causes a disturbance of brain function. Following the acute injury, over half of the youth with mTBI develop a variety of signs and symptoms including physical symptoms, such as headache, cognitive symptoms, such as difficulty concentrating, and behavioral changes, such as irritability. These can last from several minutes to months.[2] This dysfunction is commonly referred to as post-concussion syndrome (PCS).[3-6] The NIH has deemed mTBI as a societal burden due to the volume of injuries, as well as the risk of persistent neurocognitive sequelae.

Immediately following mTBI, headaches (30-58%), fatigue (19-78%), and dizziness (17%) are the predominant physical symptoms.[3-5, 13, 14] Most symptoms improve with time. Prospective follow-up data suggest that about 60% of children with mTBI meet criteria for PCS at one week following the injury, whereas 30% do at one month, and 10% continue to meet criteria at 3 months post-injury.[3, 5, 6, 9, 15, 16] Acute symptoms of headaches[5] and dizziness[17] predict the development of PCS and protracted recovery, respectively. Increased symptom awareness and management could improve outcomes and shorten the duration of symptoms, thereby reducing youth and family distress. SMART integrates online, real-time symptom and activity tracking with individualized management and activity guidance. This type of daily monitoring and feedback is only feasible online given the recommended activity restrictions and the inherent difficulties in returning to the health care provider daily.

Behavioral symptoms following mTBI are also pervasive and can include emotionality, difficulty concentrating, irritability, anxiety, and frustration.[4, 12-14] In fact, behavioral sequelae following mTBI have been reported by families as more stressful than the injury itself.[18] Premorbid personal, social, and environmental factors are important determinants of behavioral symptomatology and outcomes following mTBI.[19-23] Both anticipatory guidance and cognitive-behavioral therapy for the patients and their families reduce the behavioral consequences of TBI.[10, 12, 24] In one of the only pediatric mTBI treatment studies to date, Ponsford and colleagues[12] compared the relative efficacy of an informational booklet outlining common symptoms of mTBI and strategies for addressing them relative to usual care in 119 children with mTBI. At three months post-injury, individuals who did not receive the booklet had higher levels of PCS symptoms, behavioral symptoms and stress than did those that received the information. Currently, all children with mTBI discharged from our ED receive comprehensive instructions detailing symptoms, management, and guidelines for returning to activities. Additional interventions directed at both patients and families, such as the treatment modules designed by Wade[25, 26], have been shown to address misconceptions about brain injury[27], alleviate parental fears[7], provide coping skills to patients and families[25, 28], and reduce executive dysfunction[29] and behavioral symptoms[30]. Based on these findings, we will incorporate these interventions into our SMART program to further inform patients and families about mTBI and equip them with strategies to manage symptoms and effectively cope, thereby setting the stage for positive recovery. It is our goal to reduce the functional impairments associated with mTBI including school absences.

mTBI is an acute event with heavy initial symptom load which is managed primarily in outpatient settings. An innovative web-based therapy may be the ideal mode of intervention delivery because it can provide cost-effective access to evidence-based healthcare for youth with mTBI and their families, while reducing barriers to access such as transportation, distance, and time as compared to standard office-based programs. Reviews of web-based interventions have demonstrated positive effects on healthcare management across populations with moderate effect sizes.[31] As of 2009, 93% of children between 12 and 17 years of age were online, and 31% were seeking health information on the internet[32], thus making teenagers ideal targets for web-based treatments. Research by Dr. Wade (Co-I) involving youth with complicated mild to severe TBI has demonstrated the feasibility of web-based

therapy with this population, as well as its efficacy in improving executive dysfunction and behavioral symptoms relative to access to web-based education alone.[25, 26, 28-30, 33, 34] This work coupled with the broader literature on web-based interventions, underscore the potential merit of the proposed SMART intervention. This intervention has the potential to dramatically reduce the functional impairment associate with mTBI in Ohio through cost-effective, web-based treatment.

### Historical perspectives on the topic of this report

Effective treatments targeted at reducing the impairment would have a significant public health impact; however, for youth there are only 3 published mTBI treatment trials to date.[7-10] A report to the Congress on mTBI published by the CDC[11] and proceedings from the WHO Collaborating Centre Task Force on mTBI[8] highlighted this lack of evidence-based treatment strategies and called for more trials investigating treatments. Current best evidence suggests that a combination of symptom management, psycho-education, stress management, relaxation, and cognitive behavioral therapy may be effective in reducing morbidity from mTBI.[8-10, 12] We integrated these strategies into an innovative, online treatment program, Self-Monitoring Activity-restriction and Relaxation Training (SMART), to reduce the functional impairments associated with mTBI in youth.

This project is highly innovative because it links youth recovering from mTBI and their families in the days immediately following their injury with online evidence-based therapy and "live" management of activity levels based on current symptom status. Given the compressed time course of recovery and the recommendation of limited activity following the injury, this web-based intervention may be the most feasible approach to delivering a timely, family and patient-focused individualized intervention as compared to a handout in the ED or an outpatient visit several weeks after the injury. The multimodality of SMART allows teenagers to lie in bed with a laptop and listen as the modules are read to them. It also allows integration of self-monitoring exercises and video-clips which are not possible with written interventions such as those of Ponsford[20] or phone follow-ups. This study also provides the foundation for the use of technology-driven outpatient treatment programs for children with acute illnesses and injuries who need intensive therapy initiated immediately after discharge from the ED.

### A brief review of the current status of the topic in Ohio, the surrounding states, and nationally

Traumatic brain injuries are the leading cause of death and disability for Ohio children. Within Ohio, over 25,000 children 18 years of age and younger are evaluated in ED annually, and this number is increasing each year. About 75-85% of these injuries are referred to as "mild" traumatic brain injuries (mTBIs) or concussions. Currently we are unaware of any other treatment modalities in Ohio for these vulnerable children. We proved that our innovative web-based therapy is an ideal mode of intervention delivery because it was acceptable by both patients and children and it provided cost-effective access to evidence-based healthcare for youth with mTBI and their families, while reducing barriers to access such as transportation, distance, and time as compared to standard office-based programs. We fell that is intervention will be able to put into place for inflicted children in many different settings. We hope that this intervention will dramatically reduce the functional impairment associate with mTBI in Ohio through cost-effective, web-based treatment.

### Future trends, both regionally and nationally

The treatment program we designed will be able to put into many different types of settings that manage children with TBI. We are in the process of final data analysis and anticipate completion and

publication of these results over the next 6 months. We have a series of grants we plan to submit it in the next 6 months aimed at further refinement of the program as well as gathering additional evidence for the effectiveness of the intervention. Following that, we would like to make our program available to providers who care for children with TBI both regionally and nationally.

Based on feedback from our study, we plan to improve the web interface of the application to improve its format and make it more user friendly with decreasing "word" text and increasing graphics and animation of the content. In addition, we plan to conduct a randomized control trial to prove the effectiveness of this program in reducing symptom burden and decreasing the time to activity re-engagement.

### Financial issues and considerations

We had some financial issues during the granting period due to many issues with staff changes and slow requirement. These set up behind on our desired timeline. In attempt to further our work, we did apply for several other grants during the time period of this grant. These are listed below.

**Grants from this work** (Please specify: Submitted, Awarded)

1. Submitted February 1, 2014. NOT FUNDED. Principal Investigator is Glang A. "Next STEP: Improving Management of TBI in Transition-age Youth". National Institute on Disability and Rehabilitation Research (NIDRR). This multi-faceted intervention incorporates SMART with Dr. Glang's school based re-integration interventions allowing us to comprehensively address TBI management in the school for transition-age youth.
2. Submitted in January 2013. NOT FUNDED. Principal Investigator. Babcock L, Wade S, Kurowski B, Dexheimer J. The SMART Innovation. CCHMC Innovation Fund. $200, 000. To refine, upgrade, and improve marketability of current SMART intervention program for children with mTBI. 07/01/2013-6/30/2014.
3. AWARDED. Principal Investigator. Babcock L, Wade S, Kurowski B, Dexheimer J. Development and Pilot Trial of the SMART Intervention for Children with Mild Traumatic Brain Injury. $69,169, 10% funded effort. 07/01/12 – 06/31/2014. Place Outcomes Research Award. Cincinnati Children's Hospital Medical Center. The aim of this project is to build and refine the Self-Monitoring Activity-Restriction and Relaxation Treatment (SMART) program with the ultimate goal of reducing the functional impairments arising from mTBI.

### Education and training issues and considerations

There were no educational or training issues. We have disseminated the results of this work already in many different settings as listed below. Within the next year, we plan to further disseminate these results by publishing them in high impact journals.

**Peer Reviewed Manuscripts**

1. Manuscript Submitted. Judith W Dexheimer, Brad Kurowski, Shilo H Anders, Shari L Wade, Lynn Babcock. Usability Evaluation of SMART application for youth with mTBI. Journal of Medical Internet Research. Submitted September 2014.
2. In Progress. Daily Symptom and Activity Levels during Engagement with a Web-based Intervention for Children with Mild Traumatic Brain Injury. Brad Kurowski, Shari L Wade, Judith W Dexheimer, Jenna Gilb, Lynn Babcock.
3. In Progress. Effect of a Web-based Intervention for Children with Mild Traumatic Brain Injury on Outcomes. Lynn Babcock, Brad Kurowski, Judith W Dexheimer, Jenna Gilb, Shari L Wade.

4. In Progress. Satisfaction and Adherence with a Web-based Intervention for Children with Mild Traumatic Brain Injury. Jenna Gilb, Judith W Dexheimer, Brad Kurowski, Shilo H Anders, Shari L Wade, Lynn Babcock.

**Peer Reviewed Abstracts**

1. Presentation. Brad Kurowski, MD, MS Lynn Babcock, MD, MS Shari Wade, PhD, Judith Dexheimer, PhD, Nicole McClanahan, BA. **A "SMART" Approach to Managing Concussion:** Development and Pilot Trial of a Web-Based, Self-Monitoring Activity-restriction and Relaxation Training (SMART) Program for Kids with Mild Traumatic Brain Injury (mTBI). Telehealth Interventions for Pediatric Brain Injury. The International Society for Research on Internet Interventions (ISRII), 6th Annual Conference. May 18, 2013.
2. Poster. Judith W Dexheimer, Brad Kurowski, Shilo H Anders, Shari L Wade, Lynn Babcock. Usability Evaluation of SMART application for youth with mTBI. Pediatric Academic Society 2014 Annual Meeting. May 2014.
3. Abstract submitted. Brad Kurowski, MD, MS, Shari Wade, PhD, Judith Dexheimer, PhD, Jenna Gilb, BS, Nanhua Zhang, PhD, Lynn Babcock, MD, MS. Potential benefits and feasibility of a web-based intervention for mTBI in adolescents: a pilot study. Association of Academic Physiatrists. Submitted September 2014. Meeting date March 2015.
4. Abstract in progress. Effect of a Web-based Intervention for Children with Mild Traumatic Brain Injury on Outcomes. Lynn Babcock, Brad Kurowski, Judith W Dexheimer, Jenna Gilb, Shari L Wade. To be submitted November 2014 for Pediatric Academic Society Annual Meeting, April 2015.
5. Abstract in progress. Satisfaction and Adherence with a Web-based Intervention for Children with Mild Traumatic Brain Injury. Jenna Gilb, Judith W Dexheimer, Brad Kurowski, Shilo H Anders, Shari L Wade, Lynn Babcock. To be submitted November 2014 for Pediatric Academic Society Annual Meeting, April 2015.

### Legislative and regulatory issues and considerations

At this time there are not current legislative or regulatory issues that came up. While designing program, there were some regulatory concerns about whether this was a treatment that required additional oversight from the US Food and Drug Administration. In addition, there were concerns about us giving medical advice about return back to sports. We clarified our approach. We ensured that our approach was to provide up to date information about mTBI and provide anticipatory guidance. We made sure to inform participants that they still needed to seek traditional medical advice and clearance before returning back to sporting activities.

## Data and information issues and considerations

Throughout the grant period there have been multiple challenges in maintaining timeline goals and deliverables. Most notable setbacks were due to personnel changes within the divisions of Emergency Medicine, Physical and Rehabilitative Medicine, and Biomedical Informatics. This resulted in several changes in research assistants (5 changes), data managers (change from ED based to CCHMC data team) and program designers (3 different design teams). These changes caused multiple delays in completion of project tasks. We continued to have biweekly meetings with team members to move the study forward.

Enrollment was slower than anticipated and this was primarily due to having a low number of eligible patients present to the ED. Concussions have seasonal variation with the late summer/ early fall having the greatest frequency. Our program was not ready for use until the late fall of 2013. Recruitment in a busy emergency department with competing demands also presents challenges. Additionally, we have reviewed the screening log and assessed the top reasons why patients were deemed ineligible. One of the top reasons for ineligibility was that the patient presented to the ED greater than 24 hours after the injury. In an effort to increase our numbers, we decided to extend the time after injury to 48 hours. There were also some challenges associated with the completion of study follow-up. In an effort to resolve this issue we incorporated more frequent reminders to participants via email or phone and by created a detailed guide for participants that explains how and when to complete the study procedures.

Unfortunately due to the combination of unavoidable delays and slow enrollment, we were only able to complete the open pilot phase of the program and we did not get the opportunity to complete a small randomized clinical trial. We plan to publish the results of our open pilot and secure additional funding to complete a randomized clinical trial to prove the effectiveness of the program to reduce symptom burden following an injury.

The last challenge we came across was the issues with the program itself. We received positive feedback about the content of the program itself; however, we received negative feedback about the format and delivery of that content. In order to improve the format and delivery of the program, we feel that we need a commercial web design partner. To this end, we plan to submit a NIH Small Business Innovation Research (SBIR) in December 2014 and a grant application to the CCHMC Innovation Fund in January 2015.

## An analysis of the researcher's findings

**For Aim 1: Refine SMART a web-based intervention providing real-time individualized symptom management and cognitive-behavioral skills, for youth ages 11 to 18 years with mTBI.**

<u>The Refinement</u>

We worked with Biomedical Informatics to refine our program interface for the youth and their parents. The final SMART program consists of three components. The first component consists of a symptom and activity tracker that provides interactive, individualized activity recommendations based on current symptom burden and time since injury based on the current best evidence of stepwise return to activities. The second component consists of cognitive behavioral treatment modules also based on the current best evidence of therapeutic interventions. The third component consists of weekly assessment of health, behavioral and disability outcomes. In addition, we have designed a program to capture

usage logs that will allow us to monitor time spent on modules and number of times the program has been accessed.

We detailed the overall program navigation template. We established password protected login screens for patients and parents, designed the symptom and activity tracking programs, as well as detailed the logic for activity progression based on daily symptom burden, and the logic for progression through the modules based on symptom burden and time since injury. We refined the existing 8 modules that are detailed in Table 1. These modules were vetted amongst experts who care for children with mTBI. Each module contains didactic information, videotapes of youth talking about mTBI and modeling skills, and interactive exercises to practice skills. Videos were obtained from youth with a recent history of mTBI during a key informant interview about their injury and experiences. Snippets of the tapes were strategically placed into the modules. These modules have been primarily geared toward the patient; however, we staged so that parents will also be able to access the content and knowledge imparted in the modules. Finally, we built a REDCAP database to capture emergency department enrollment information, as well as weekly outcome measures. The logic for the timing of the measures is integrated into the SMART program to pull the patient out of the program into REDCAP to complete the assessments.

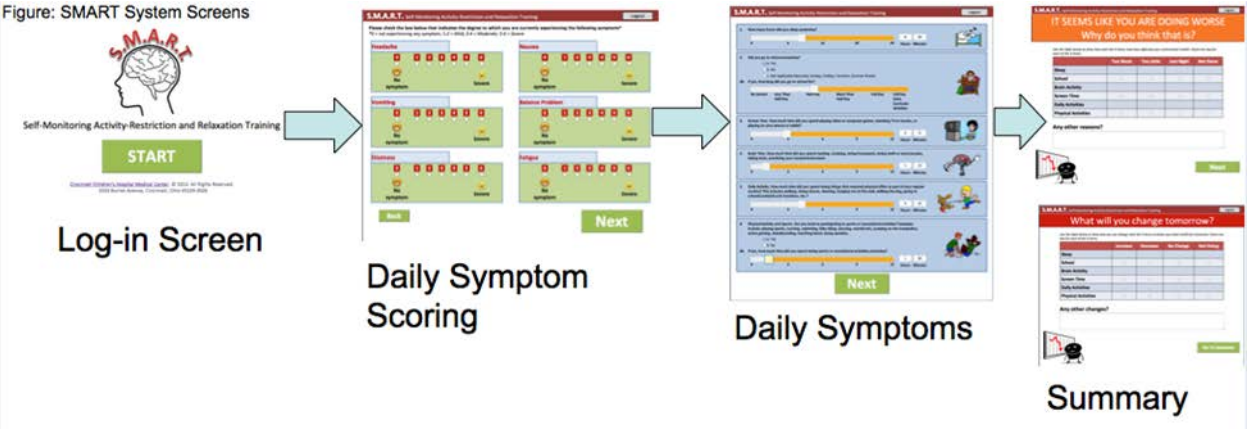
**Table 1. SMART Modules**

| **Module** | **Skills Addressed** |
|---|---|
| 1 Introduction and Self-Monitoring | A basic overview and introduction to the program and mTBI recovery |
| 2. Symptom Maintenance | Information about common symptoms, timelines for recovery, and strategies for coping |
| 3. Staying positive | Teaches cognitive reframing strategies to address worries and negative cognitions about symptoms and missed activities |
| 4. Managing stress | Provides instruction in relaxation and imagery to more effectively handle stress and manage headaches and other pain |
| 5. Stop, Think, Problem Solve | Provides training in 5-step problem solving heuristic (Aim, Brainstorm, Choose, Do It, Evaluate) to address concerns regarding PCS-related issues |
| 6. Returning to school/activities | Provides guidelines and strategies for working with the school and other non-athletic activities to ensure a successful re-entry without symptom exacerbation. Module also included a printable table explaining a step-wise approach to return to activities. |
| 7. Taking Care of You | Provides strategies for healthy functioning including adequate sleep, proper nutrition, and hydration |
| 8. Staying Focused | Provides tips for minimizing distractions and coping with attention and concentration difficulties. |

<u>The Program</u>

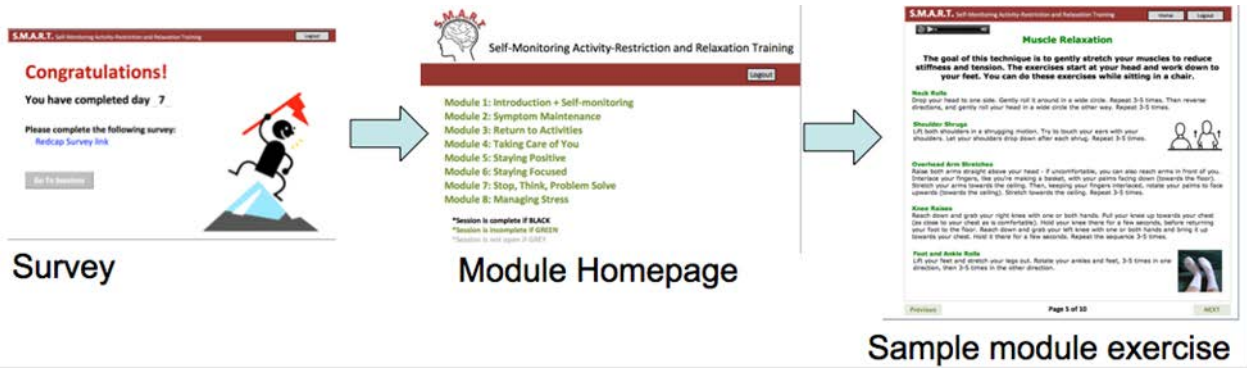
The final design of the SMART application is presented in Figures 1 and 2. Youth with mTBI are instructed to log into the SMART application daily after their injuries following discharge from the ED. Once logged into the system, the user is asked to rate their symptoms using questions contained on the Post Concussion Symptom Score (PCSS). The user's total PCSS score is compared to his or her previous score from their last logon or the "normal" score for their gender, if this is the user's first time on the

website. The user is then shown a summary screen with feedback (i.e. the symptoms are better, worse, or about the same) regarding his/her symptom levels. Screen shots are shown below.




To allow the user to link his/her behavior to changes in mTBI symptoms, the user is asked to rate his/her sleep, school, brain activity, screen time, daily activities, and physical activities on the following scale: increase, decrease, no change, and not doing. After completing these ratings, the user is asked to and asked to indicate what behaviors may have contributed to the symptom changes and what she/he will change tomorrow to reduce symptoms. This approach encourages real-time self-monitoring and increased awareness of the association between behavior and symptoms. After completing these daily evaluations, the user is directed to the psychoeducational modules.

Screen shots of the modules are shown below. Module title text is displayed as gray if the module is not open, green if the module is open to be used and black if the participant has completed the module. The introduction module is available to all users 24 hours after injury upon logging in to the system. The modules are released based on logic incorporated date of injury; symptom burden based on the PCSS completed on that logon date, and information that we felt would be most pertinent at that time frame following the injury. By one week post injury, all modules are available for completion.




<u>Stakeholder Input</u>

We held one focus group to explore the needs of the patients with mTBI and the physicians caring for them. One consisted of 3 parents whose child had sustained a recent traumatic brain injury. We tried to hold a second focus group but there were difficulties with convening the group. The resolution to really focus on the usability testing was incredibly helpful because we were also able to gain some of the

information that we would have received in the focus groups just through our conversations with the families. For example, we learned that some families had experienced concussions in their family before and did not have the type of tailored information that our program will hopefully provide. We learned that the information we are going to provide families would have been useful to those already impacted by concussion and mTBI. Additionally, in eliminating the focus groups, the study team has decided to instead of having a provider focus group, we will now be contacting primary care providers to inform them of their patients' involvement with the study and to complete a follow up questionnaire to physicians to get their feedback about the program. These results are in the process of analysis. We think that we can get useful information from the physicians who are involved with the care of our patients and tailor our program in the future to meet their needs as well.

Usability Testing

A summative usability evaluation was conducted to assess and, if appropriate, modify the SMART system until we achieved adequate usability (average System Usability Scale score (SUS) > 68).

*Methods:* Children ages 11-18 years presenting to the emergency department with a mTBI were recruited for usability testing. Usability testing was performed post-injury following symptom resolution. System usability was assessed by observing the child and their parents interacting separately with program modules for 60 minutes. Participants were asked to think aloud while performing specific tasks. Each session was audio-recorded and transcribed. Upon completion of the prescribed tasks, each participant completed the 10-item SUS to assess usability. Data were compiled and analyzed to examine the system's strengths and opportunities for improvement. Iterative improvements to SMART program were implemented based on this evaluation.

*Results:* A total of 8 participants, 4 child/parent pairs, completed the usability testing. The average age of the children was 13.0 years old (standard deviation=1.8); the parents were an average of 41.5 years old (standard deviation = 6.2). The average time since injury to testing was 21 days (range: 6-39 days). The average PCSS score was 15.3 (range: 1, 52). The mean SUS score was 85; children's average score was 81(standard deviation = 22.8) while parents' average score was 89 (standard deviation =10.7). The analysis of the interview transcripts and the feedback given during testing revealed two main themes: (1) the system included too much reading and (2) the system provided valuable information for children and participants that were not otherwise readily obtainable. Below are select user feedbacks.

**Table: Select User Feedback on the SMART System**

| **Positive** |
|---|
| I liked the audio recording of reading the modules (parent) |
| Tailored aspect of the program (parent) |
| Provided information that wasn't otherwise easily available (parent) |
| [Enjoyed] videos of concussed children (parent, child) |
| **Negative** |
| Worried that the timeline to move through is too quick (parent) |
| Too much reading (child) |

*Conclusions:* High SUS scores indicate satisfactory usability and acceptability of the SMART program by children with a history of mTBI and their parents.

Program Changes:

As a result of the feedback, we decreased the amount of text and added an audio file allowing the user to listen to rather than read the text of every page. By assessing the usability of the system, we were able to improve the end-product and make the intervention more useful for the study population. We made color corrections and adjustments and fixed some minor typographic errors to help improve clarity. In response to the qualitative feedback from participants, researchers modified SMART to include an audio file in every module and improved the system's aesthetic properties.

**For Aim 2: Evaluate the feasibility and preliminary efficacy of the SMART program (from Specific Aim 1) through an open test pilot with up to 35 youth ages 11 to 18 years who present to the ED with mTBI.**

SMART was then put into production and enrollment for the open pilot began on October 30th, 2013 and was stopped on July 30, 2014 due to the end of the funding cycles for both Ohio EMS and CCHMC Outcomes Grants. We screened 578 patients for the study. 56 patients who were deemed eligible were approached about the study. The consent rate was 37.5%. Twenty-one patients were enrolled and completed baseline data collection in the ED. 12 patient/parent dyads completed most interval assessments over the month. Patient level follow-up completion data is provided in the following table.

| Study ID | Enrollment Date | Baseline Completed | 1w Child | 1w parent | 2w child | 2w parent | 4w child | 4w parent |
|---|---|---|---|---|---|---|---|---|
| 1 | 3-Nov | Y | N | N | Y | Y, partial | Y | Y |
| 2 | 21-Nov | Y | Y, partial | N | Y | N | N | N |
| 3 | 3-Dec | Y | Y | Y | Y | Y | Y | Y |
| 4 | 8-Jan-14 | Y | N/A | N/A | N/A | N/A | N/A | N/A |
| 5 | 18-Jan-14 | Y | N/A | N/A | N/A | N/A | N/A | N/A |
| 6 | 12-Feb-14 | Y | Y | Y | Y | Y | Y | Y |
| 7 | 24-Feb-14 | Y | Y | Y | Y | Y | N | Y |
| 8 | 13-Apr-14 | Y | N | Y | Y | Y | Y | Y |
| 9 | 21-Apr-14 | Y | N | N | | | | |
| 10 | 24-Apr-14 | Y | Y | Y | N | Y | N | Y |
| 11 | 30-Apr-14 | Y | Y | Y | Y | N | Y | N |
| 12 | 6-May-14 | Y | Y | Y | Y | Y | Y | Y |
| 13 | 13-May-14 | Y | N/A | N/A | N/A | N/A | N/A | N/A |
| 14 | 15-May-14 | N | N/A | N/A | N/A | N/A | N/A | N/A |
| 15 | 29-May-14 | Y | N/A | N/A | N/A | N/A | N/A | N/A |
| 16 | 1-Jun-14 | Y | Y | Y | Y | Y | Y | Y |
| 17 | 2-Jun-14 | N | Y | Y | Y | Y | Y | Y |
| 18 | 5-Jun-14 | Y | Y | Y | Y | Y | Y | Y |
| 19 | 16-Jun-14 | Y | N/A | N/A | N/A | N/A | N/A | N/A |
| 20 | 20-Jun-14 | Y | N/A | N/A | N/A | N/A | N/A | N/A |
| 21 | 30-Jun-14 | Y | Y | Y | Y | Y | Y | Y |

The data from both our RedCap database (ED and interval outcome assessments) and the BMI user interface (daily symptom and activity levels, as well as program usage statistics) were cleaned and merged into one dataset. We have started on three additional analyses that will form the basis of three additional papers. Additional results will be available as we complete these analyses. We anticipate completion of these papers by the end of 2014. These include:

1. Daily Symptom and Activity Levels during Engagement with a Web-based Intervention for Children with Mild Traumatic Brain Injury.
2. Effect of a Web-based Intervention for Children with Mild Traumatic Brain Injury on Outcomes.
3. Satisfaction and Adherence with a Web-based Intervention for Children with Mild Traumatic Brain Injury.

We submitted an abstract to the American xxx containing some preliminary data focused on the daily changes as described below. In addition, we will submit abstracts to the 2015 Pediatric Academic Society Annual Meeting containing data pertinent to papers 2 and 3 as listed above.

<u>Daily Symptom and Activity Levels during Engagement with a Web-based Intervention for Children with Mild Traumatic Brain Injury.</u>

*Objective:* The objective of this study was to evaluate the changes in the daily symptom and activity levels during engagement with an interactive, web-based intervention that incorporates symptom and activity monitoring, as well as anticipatory guidance and cognitive-behavioral therapy principles about mTBI.

*Methods:* Prospective, open pilot of the Self-Monitoring, Activity-Restriction and Relaxation Treatment (SMART) intervention. Repeated-measures using generalized linear mixed modeling were used to analyze recovery over the 4-weeks post-enrollment.

*Participants:* 21 adolescents age 11-18 years with a mTBI who presented to the emergency department (ED) from Nov 2013 to June 2014 within 96 hours of injury.

*Outcome:* Primary: Daily post-concussion symptom score (PCSS). Secondary: Daily self-reported ratings activities. Outcomes were assessed daily via a web-based system.

***Results:*** Twelve adolescents completed the study; 8 were male. Average time of ED presentation after injury was 10.3 hours. The average baseline PCSS was 25.8 and daily activity was 2.4 hours. Generalized linear mixed-effects model analysis demonstrated a fast decrease of PCSS following the intervention at a rate of 2.2 points/day that stabilized after about two weeks. Daily activities increased by 0.04 hours/day over the 4-week follow-up (p=0.24); both screen time and physical activity increased over the follow-up period, by 0.06 and 0.04 hours/day (p-value = 0.04, and 0.05), respectively.

***Conclusions:*** SMART, a novel web-based application of anticipatory guidance and cognitive-behavioral therapy, is potentially beneficial to ameliorate symptoms and modulate activities for adolescents soon after mTBI. Future research will need to determine the comparative benefits of SMART to standard care and the ideal target audience.

## Conclusions

With the funding from the Ohio Department of Public Safety, we were able to develop an innovative, cost-effective, and acceptable program aimed at decreasing the morbidity for children who sustain concussions. Our preliminary evidence suggests that this program is useful and acceptable. In addition, participants of the program experienced symptom improvement during engagement with the program.

## Recommendations

Further refinement and testing of this program will provide additional evidence for its effectiveness in reducing impairment following concussions in children.