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Clinical Study Protocol

Can targeted education impact the current standard of care in patients with mild traumatic brain injury?

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St. Michael's Hospital
Protocol Version Three

Version date: April 16, 2019

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Lists of abbreviations and terminology

mTBI: Mild Traumatic Brain Injury
PTH: Post Traumatic Headache
RPQ: Rivermead post-concussion questionnaire
PART-O: Participation Assessment with Recombined Tools-Objective
QOLIBRI: Quality of Life after Brain Injury
REDCap: Research Electronic Data Capture

Protocol Summary:

Full Title: Can targeted education impact the current standard of care in patients with mild traumatic brain injury?

Sample Size: Approximately 70 patients

Study Population: Patients seen at the St. Michael's Head Injury Clinic

Study Design: Randomized-Control Study

Study Duration: January 2018- December 2019

Study Agent/ Intervention/ Procedure: Educational

Primary Objective: Are we able to see a decrease in patients reported symptoms by 3 on the Rivermead post concussion questionnaire or RPQ-3 and 10 on the RPQ-13 in those that receive targeted headache education in comparison to those who do not?

Secondary Objectives: When and what type of health care services do participants in this study access, how frequently and is there a difference and between the two groups.

Does education through reinforcement of appropriate lifestyle and treatment strategies translate to similar pre-injury scores on the PART-O tool at the 12-week time point.

By the end of the study, the educational intervention group will be more satisfied in various aspects of their life as measured by the QUOLIBRI compared to their week 0 scores.

Endpoints of the study: Significance will be observed if patients reported symptoms decrease by 3 points on the RPQ-3 and 10 on the RPQ-13.

2 Administrative Information

Title of Study: Can targeted education impact the current standard of care in patients with mild traumatic brain injury?

Date of REB Application: June 29, 2017

Trial Registration: NCT03391583

Source of Funding: PSI grant total funding of 20,000: Approval pending

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Sponsor and Funder: This funding source had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results

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3 Introduction

3.1 Background

According to Chen et al. (2002), the annual medical costs of patients hospitalized with a traumatic brain injury in Ontario in the first follow-up year were approximately $120.7 million between 2004 and 2007.[3] Preventable injuries cost the Canadian economy $27 billion per year, with more than 3.5 million emergency room visits and without intervention by 2035 will cost $75 billion per year. [11] Acute care cost accounted for 46-65% of the total treatment cost in the first year overwhelming all other cost components. [3] Traumatic brain injuries is an expensive neurological disorder; the most common type of brain injury health care providers will encounter in the outpatient setting is mild traumatic brain injury. We define mild traumatic brain injury (mTBI) as a physiological disruption of brain function, manifested by any period of loss of consciousness, loss of memory for events immediately before or after the accident, alteration in mental state at the time of the accident and focal neurological deficit(s) that may or may not be transient. The severity of the injury cannot exceed a loss of consciousness of greater than 30 minutes, a Glasgow Coma Scale (GCS) no less than 13–15; 30 minutes post injury and posttraumatic amnesia (PTA) not greater than 24 hours.[13] Although many patients with mTBI have rapid symptom resolution, there is a specific subgroup of patients referred to as the "miserable minority" who experience chronic symptoms that present as a therapeutic challenge. Unfortunately, there has been much discussion and great controversy surrounding the mere existence of a "post-concussive syndrome," with comparatively less attention being paid to development of effective treatments for affected individuals[1]

Clinical and research findings suggest 4 main symptom constellations comprising the clinical presentation of chronic mTBI concussive syndrome: (1) cognitive symptoms, including reduced attention, mental control, executive dysfunction, and recall deficits secondary to reduced attention; (2) physical symptoms, such as headache, sensory changes, and cognitive/physical fatigue; (3) psychiatric sequelae, including depression, anxiety, and posttraumatic stress disorder; and (4) emotional dysregulation [1]. Of the many manifestations of post concussive syndrome listed above, headache is an integral and consistently endorsed symptom in this patient population. It is often the symptoms that is managed and understood the most poorly. Therefore, it seemed fitting that for this study post traumatic headache would be the symptom to analyze. At times, it can be difficult to classify headache, however the current standard is to use the definition set by the International classification of Headache disorders third edition-beta (ICHD-3). Post traumatic headache is defined as a secondary headache disorder in which the headache is reported to have developed within 7 days after either an injury to the head, regaining of consciousness following the injury to the head or discontinuation of medication(s) that impair ability to sense or report headache following the injury to the head. An acute headache is classified as lasting 3 months with the definition shifting to persistent if the headache is present after this time period. [5] When not properly managed post traumatic headache can severely lengthen the time patients take to return to their baseline functioning if ever. Because of their protracted course this patient population has a greater

tendency to access health care resources. We know that among prevalent cases with traumatic brain injury aged younger than 65 years, the majority of the costs associated with health system use were attributable to hospital care (46.0%), physician and other health care professional services (27.8%) and prescription drugs (10.1%). [10] The obvious goal is to reduce the burden on the healthcare system, empower patients to make informed healthcare decisions, facilitate return to the workforce and to improve quality of life after injury.

In a preliminary study by Kirkham et al. (2016) their group found that despite treatment directed at headache, depression and fatigue, patients who were at least 6 months out from injury had persistent high scores on the Rivermead post-concussion symptoms questionnaire along with high scores on the fatigue severity scale and the patient health questionnaire. [8] Education surrounding head injury is not standardized and remains inconsistent. Much of the literature surrounds the pediatric population pertaining to sport related injuries. There is a large knowledge gap in the adult population who arrive to the ER after a mild traumatic brain injury and in the same subset of patients who present later on into the chronic phase of their symptoms. We aim to build upon Kirkham's work with the idea that if we can empower and educate patients, their anxiety levels will become less of a confounder on recovery. We will also be looking at level of activity and severity of headache i.e. is the level of the headache the same but the level of activity higher. Previous studies have attempted to show that early educational information in the form of expectation management is a means for reducing long-term mTBI symptoms. The CDC recommends monitoring symptoms and intervening in the acute stage (less than 3 months) to ensure the best possible outcome. [3] Typically, psychoeducational treatment consists of the early provision of information related to the mild TBI diagnosis and possible symptoms, normalization of symptoms, reassurance of positive expectation of recovery, and education on coping strategies. [9]A RCT completed by Wade et al. showed that when individuals receive early routine follow-up that included education plus targeted interventions, patients experienced significantly less disruption of social and functional ability and fewer or less severe post concussive symptoms than individuals receiving usual hospital services.[13]

Based on these studies, the question remains as to how best consistently treat this unique patient population. We know that many mTBI patients are not consistently being referred to a specialized clinic directly from the ER and of those patients they may present months later to their primary care providers, walk-in clinics or the ER after their symptoms persist. Our goal is to set in place a standard of care that will decrease symptom reporting and improve functional outcomes, starting with a patient population that is already being provided a multi-disciplinary care approach. Allowing the patient to experience improved self-efficacy with appropriate levels of expectations and perceived improvement in quality of life. We also hope to show that we can reduce the number of health care related visits (ER, Walk-in clinics etc.) that patients with post-traumatic headache will access in comparison to the current standard of care. Future goals will include using this approach to assess other post concussive symptoms in the multi-disciplinary clinic along with developing educational material that provides a clear and consistent message when treating head injury patients. We would also like to expand this education model to different clinic settings in order to provide this level of care to patients more acutely and ultimately reduce wait times for subspecialty clinics.

3.2 Aim of the Study

The aim of the study is to ask the question as to whether or not targeted education will decrease symptom reporting in those suffering from post-traumatic headache after mild traumatic brain injury. The primary endpoints being measured include symptom reporting, perceived improvement in quality of life, utilization of health care services and return to baseline level of functioning.

This study will compare two groups of patients that are in the chronic phase (12 weeks and on) of their post-traumatic headache symptoms.

This model of educational intervention aims to change the way we deliver education material to this specific subset of patients. The goal is to apply this method of education to individuals with other mild-traumatic brain injury symptoms that can be realistically provided in a primary health care setting, ultimately reducing wait times for subspecialty clinics. Questions asked throughout the study will be provided by common data elements that will be used not only to standardize the study but to promote further research in the field across multiple sites in the province.

3.3 Study Hypothesis and Objectives

3.3.1 Hypothesis

Providing targeted education headache education to patients who have suffered from mild traumatic brain injury will reduce symptom scoring on the Rivermead Concussion Questionnaire by week 12 of the study.

3.3.2 Primary Objective

Are we able to see a decrease patient reported symptoms by 3 on the Rivermead post-concussion questionnaire or RPQ-3 and 10 on the RPQ-13 in those that receive targeted headache education in comparison to those who do not?

3.3.3 Secondary Objectives

3.3.3.1 Key Secondary Objectives

When and what type of health care services do participants in this study access, how frequently and is there a difference and between the two groups.

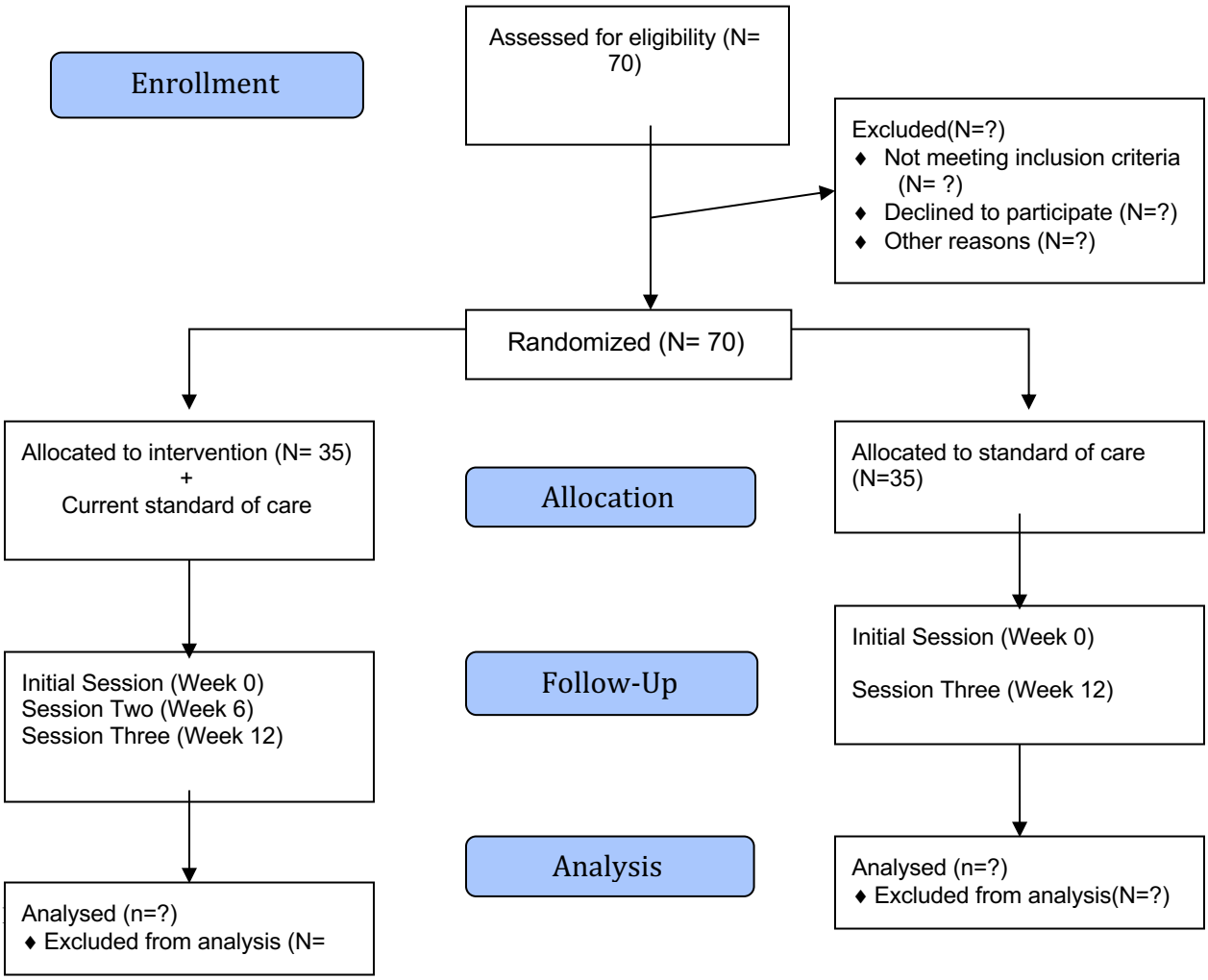
3.3.3.2 Other Secondary Objectives

- Does education through reinforcement of appropriate lifestyle and treatment strategies translate to similar pre-injury scores on the PART-O tool at the 12-week time point.
- By the end of the study, the educational intervention group will be more satisfied in various aspects of their life as measured by the QUOLIBRI compared to their week 0 scores.

3.4 Trial Design

This study is a blinded randomized control trial, which is the optimal trial design to determine whether a cause-effect relationship exists between our educational intervention and the current standard of care.

3.4.1 Post Traumatic Headache Education Study Flow Diagram



3.4.1.1 Figure 1: Flow diagram of patient enrollment, allocation and follow up.

3.5 Methods: Participants, Measures and Outcomes

3.5.1 Eligibility Criteria

3.5.1.1 Inclusion Criteria

Inclusion criteria will be individuals between the age of 18- 65 years of age with a chronic mTBI based on CDC criteria. They must have the ability to give consent, speak English with awareness that they will need to be contacted at various time points, and must have access to email. We will include patients that score 3 or more on the RPQ either in the ER or during their initial assessment. They must be medically stable.

3.5.1.2 Exclusion Criteria

Patients will be excluded from the study if they have a documented history of moderate to severe traumatic brain injury. If they have a prior history of other neurological (i.e. Epilepsy, MS, Alzheimer's Disease), psychiatric (i.e. Psychotic disorder or other history of a mental health disorder) or substance abuse disorders. Subjects will be excluded if they have no fixed address or are incarcerated, as that would hinder follow up. The St. Michael's Hospital Head Injury Clinic Steering Committee and the St. Michael's Hospital Research Ethics Board will be required to approve the study.

3.5.2 Interventions

3.5.2.1 Educational Intervention

Participants in the education arm of the study will be provided with three PowerPoint presentations. Material for these slides has been adapted from material developed by the Ontario Neurotrauma Foundation. Topics to be addressed will surround post-traumatic headache and will include information regarding common symptoms, timeline for improvement, red- flags and when to seek medical attention. The first session is conducted in-person to provide participants with an outline of the study and to discuss the first PowerPoint session. For the remainder of the sessions, the PowerPoint slides will be emailed with follow up telephone or in person discussions with patients to ensure that they received the material, understood it and could open it. At the 12-week time point (post study enrollment) we will also ensure that patients have filled out the survey's via REDCap and perform an Exit interview. If patients return to the clinic for subsequent follow up visits, we will attempt to provide the session at the follow up visit that closely relates to the time point stated above.
For those patients not allotted to the education arm, at the end of the study they will be offered the educational material should they wish to review it.

3.5.2.2 Summary of education by session: PowerPoint slides will be split into three distinct sections.

Initial session: (0 weeks): (In person) We will outline the study. Approximately 30 minutes in duration.

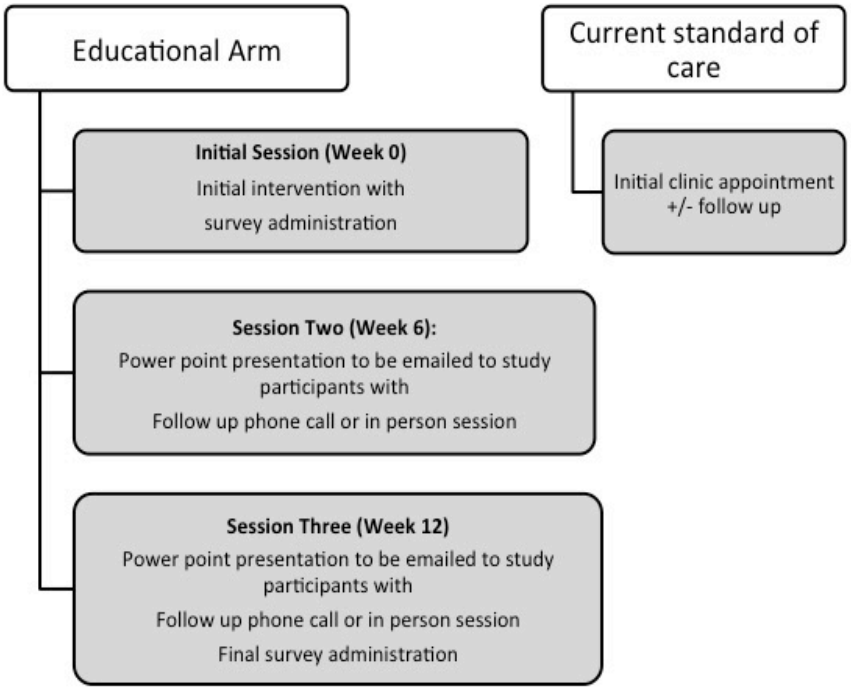
- Review inclusion/exclusion criteria
- Explain study goals
- Obtain written/verbal informed consent
- We will cover topics such as defining the basic anatomy and the consequences of head trauma. We will include common symptoms along with when to seek medical guidance, medications to avoid and helpful lifestyle and treatment tips. Patients will be provided with links to approved websites.
- Prior to this session
    - Complete demographic information, medical history, trauma history and participant contact information (email or phone) will be gathered. If patients are identified in the ER, this information will be provided by the Triage nurse and forwarded to the research assistant who will be responsible for follow-up and providing the study materials.
    - Rivermead Post-Concussive Questionnaire (RPCSQ), PART-O and QOLIBRI (Yellow form: See Appendix) will be completed.

- *Second Session (6 weeks):* (*via email).* Explain importance of keeping brain active; define the assessment of brain activity. 10-20 minutes to review the PowerPoint. Follow up will be done 1 week later either in person, email or via telephone to ensure patients are able to open the PowerPoint and have reviewed the literature. There will be no education or discussion about current treatment regimen or symptoms. Should a patient have questions regarding their current treatment plan or symptoms, our volunteers will put patients in contact with the Head Injury Nurse. All calls will be made during clinic hours in order to help facilitate communication with the clinic.

Third Session (12 weeks)- (In person or sent via email) We will explain importance of stress, sleep, and exercise on brain function, define the influence of lifestyle on recovery. Approximate duration is 10-20 minutes. 1 week later follow up via telephone or email will occur by the methods listed above to ensure that the patient was able to open the PowerPoint. At this time we will:

- Re-verify inclusion criteria to be done by Research Assistant. There will be no education or discussion about current treatment regimen or symptoms. Should a patient have questions regarding their current treatment plan or symptoms all calls will me made when the Head Injury Nurse is available to connect with patients directly.

- Rivermead Post-Concussive Questionnaire (RPCSQ), PART-O and QUOLIBRI will be completed via telephone or email and entered via REDCap into our database. Survey data will be uploaded by student or research assistant that is unaware of the patient's randomization.
- The patients who did not participate in the education seminar will fill out surveys at week 0 and 12.



3.5.2.3 Figure 2: Breakdown of educational intervention compared to the current standard of care.

3.5.2.4 Adherence

An initial face-to-face session will take place at the initial visit with each subsequent visit either in person or via telephone. Points that will be highlighted are the importance of following study guidelines. Monetary incentive of a 10 dollar Tim Hortons gift card will be given for each survey the study participant completes in order to encourage continued engagement in the study. The gift cards will be given in person at the first session and the other gift cards will be sent in the mail once the final survey has been completed.

3.5.2.5 Concomitant Care

All patients will be seen in a tertiary level clinic. Clinicians are blinded to the allocation of the study participants. Therefore, regardless of their study allotment they will receive the current standard of care provided in the clinic.

3.5.3 Outcomes

3.5.4 Primary Outcome Measures

Targeted education provided to patients suffering from post-traumatic headache will be assessed using the RPQ. The RPCSQ is a 16-question instrument that examines post-concussion symptoms rated by the patient according to the increase in their frequency compared with premorbid levels. The total score is calculated based on 2 domains (cognitive and emotional-somatic) and ranges from 0 to 72. [7] The RPQ has been shown to measure severity of postconcussion symptoms reliably with good test-retest and inter-rater reliability for individual symptom scores. [6] Based on previous studies, splitting the RPQ into two subscale scores: RPQ-3 uses the sum of scores from three items (headaches, dizziness and nausea) and RPQ-13 uses the sum of scores of the other 13 items. Higher scores especially for the RPQ-13 subscale are associated with greater impact on lifestyle. For our study significance will be observed if patients reported symptoms decreased by 3 on the RPQ-3 and 10 on the RPQ-13.

3.5.5 Secondary Outcome Measures

For the secondary endpoints, we will analyze the frequency and type of health care patients accessed outside of their current standard of care during the 12-week study period. This will be compared to our controls and will include emergency room, family physician visits, hospital admissions and telehealth that are related to post traumatic headache symptoms.

Another end point we are interested in exploring is whether patients that are provided targeted headache education along with tertiary care has an increased frequency of social interactions in comparison to patients receiving the current standard of care. We are very interested in the hours that each patient devotes to their previous work or hobbies and we will be comparing this once again to patients in the clinic who are receiving the standard of care. This outcome will be measured using the PART-O tool which asks questions about the type and frequency of social engagements that patients may encounter each week along with the hours that patients devote to returning back to work, school or homemaking.

Lastly, we are interested in whether or not education and reassurance alter a patient's perceived quality of life after a mild-traumatic brain injury. This will be analyzed by using the QOLIBRI (Quality of Life after Brain Injury). Using this scale we hope to capture whether or not patients believe they play an active role in their health and whether or not they feel empowered to alter their health status. It will hopefully also allow us to capture what

barriers there are to a patient's recovery in regard to what negative feelings and limits they perceive; preventing them from making a meaningful recovery.

3.5.6 Sample Size

Sample size is based on alpha (2-sided significant level) of 0.05 and power of 80%. Given that the largest review study (Theeler, 2013) showed a headache prevalence of 21-100% (0.21 – 1.00) in their TBI group and 26% (0.26) in the control group with a ratio of control/cases= 1:1, sample size was computed at 28 (Educational group) and 28 (standard of care group) with total sample size of 56. We have anticipated 20% attrition and therefore we will aim to enroll 35 patients per study arm in order to maintain statistical significance. This rate is based on prior studies using the RPQ [7] and a recent study conducted at St. Michael's by Hu et al. looking at age and association with mild-traumatic brain injury symptoms[6].

3.5.7 Recruitment

Subjects will be recruited by individuals in the patient's circle of care including the emergency department triage nurse. Patients with mild traumatic brain injury will be enrolled at least 12 weeks after their injury. Recruitment of study participants fulfilling eligibility criteria will be identified and referred through the emergency room, their primary care physician or specialist to the St. Michael's head injury clinic in Toronto between January and December 2018.

3.6 Methods: Assignment of Intervention

3.6.1 Allocation

Participants will be randomly assigned to either control or interventional group with a 1:1 allocation as per a computer-generated randomization schedule using permuted blocks of random sizes. The block sizes will not be disclosed, to ensure concealment. The research assistant will not be allowed to touch the randomizing envelopes until each patient is about to be randomized.

3.6.2 Blinding

Assessments regarding clinical recovery will be conducted by an assessor who is aware of the allocation of the patients in the study. The assessor will have a template in which to follow in order to ensure that the only difference between the two groups will be to ensure that the educational arm is able to open the pdf. Those who work in the clinic will not know

the allocation of the patient in the study but we are aware that this may be discovered during clinic visits. This will be a variable to consider when we analyze the data. An employee outside the research team will feed data into the computer in separate datasheets so that the researchers can analyze data without having access to information about the allocation

3.7 Methods: Data collection, management and analysis

3.7.1 Data Collection

For all visits each patient will fill out a questionnaire (See Appendices for full surveys) using RedCap. If a patient is unable to enter the data using email directly, one of our research assistants will enter the data into the RedCap system via telephone interview. For the follow up survey if there is no response, we will attempt to contact the patient by phone three times. In regard to those patients seen in follow up in the clinic, we will ensure that they finish their follow up questionnaires after being seen by a healthcare professional to avoid unblinding. Patients' receiving the standard of care will be asked the same questions at week 0 and 12 with the same surveys as the education intervention arm of the study. A secure password protected master linking log will be able to house the patient name with study identification number.

3.7.2 REDCap Security Summary

The Applied Health Research Centre (AHRC), an academic research organization based at St Michael's Hospital, will use software called REDCap (http://project-redcap.org/) to create the web-based electronic CRF (eCRF). All study data will be securely stored on local servers at St Michaels Hospital throughout the duration of the study and for up to 10 years after the study is complete. All study subjects will be identified in the database by a unique study ID number. Linkages between the patient name/contact information and the study ID will be retained at the local site and not shared with the study DCC or outside the institution. At the end of the study (after all analyses are complete) the DCC will transfer all study datasets over to the study PI . Data will only be accessible by authorized study site personnel and authorized central DCC personnel. Authorized personnel receive a username and password which is unique, and database access is controlled by the DCC in collaboration with the Principal Investigator.

3.7.2.1 Physical Access and Security

The REDCap application is hosted locally in St. Michael's Hospitals secure data centers and has dedicated IT, database, application, and build support personnel. The SMH data centre infrastructure has several features in place to enhance the security of data, prevent data loss and mitigate downtime. These include:

· Duplicate Internet Service Providers (ISPs)

- Infrastructure distributed between two data centres
- Virtualization for added redundancy
- Data centres are accessible by designated IT staff only
- Access is logged through RFID card access and through a physical sign in page
- Redundant UPS' for backup power
- Redundant cooling systems
- Inert gas-based fire suppression system

Data will be stored on the local Storage Area Network (SAN) and will be backed up regularly and stored off-site. The data centre is designed such that there are daily backups made of all critical data. In addition, the backups are stored both locally, as well as at a remote off-site location, in the case of catastrophic failure at one location. With limited access privileges, 24 hour security, and around-the-clock monitoring, the data centre is highly secure.

3.7.2.2 Logical Access and Security

REDCap servers are accessible by designated IT staff only for administration and maintenance purposes. The REDCap application is accessible by registered (through AHRC) users only, who are restricted to accessing the projects that they are assigned to. REDCap uses standard authentication mechanisms to ensure only registered users can access the system, ensures only explicitly specified users can access any particular project and data, and furthermore, provides customizable user access for each project with controls that can be used to restrict users to write or read-only privileges on a form-by-form basis. Transmitted data is secured through the use of TLS certificates that encrypt all data sent to and from the server.

3.7.3 Primary Outcomes.

Data will be collected using the Rivermead Post Concussion Symptoms Questionnaire (RPQ): The symptoms listed on the RPQ are those most commonly reported in the published literature as post concussion syndrome (PCS). The RPCSQ is a 16-question instrument that examines post-concussion symptoms rated by the patient according to the increase in their frequency compared with premorbid levels. The total score is calculated based on 2 domains (cognitive and emotional-somatic) and ranges from 0 to 72. [7] The RPQ has been shown to measure severity of postconcussion symptoms reliably with good test-retest and inter-rater reliability for individual symptom scores. [6] Based on previous studies, splitting the RPQ into two subscale scores: RPQ-3 uses the sum of scores from three items

(headaches, dizziness and nausea) and RPQ-13 uses the sum of scores of the other 13 items. Higher scores especially for the RPQ-13 subscale are associated with greater impact on lifestyle. For our study significance will be observed if patients reported symptoms decreased by 3 on the RPQ-3 and 10 on the RPQ-13.

We will be comparing headache symptom reporting between the two groups assigning significance if patients in the education arm have a decrease in symptom reporting on the RPQ-3 by 3 and 10 on the RPQ-13.

3.7.4 Secondary Outcomes

Perceived Quality of Life: Quality of Life after Brain Injury scale
The QOLIBRI (Quality of Life after Brain Injury) is a health-related quality-of-life instrument specifically developed for traumatic brain injury (TBI). The first part assesses satisfaction level with health-related quality of life (HRQOL) and is composed of 6 overall items and 29 items assigned to 4 subscales: thinking, feelings and emotion, autonomy in daily life and social aspects. The second part is devoted to "bothered" questions and composed of 12 items in 2 subscales: negative feelings and restrictions. Responses to the 'satisfaction' items (i.e. items on the Cognition, Self, Daily Life & Autonomy, and Social Relationships scales) are coded on a 1 to 5 scale, where 1= "not at all satisfied" and 5="very satisfied". Responses to the 'bothered' items (i.e. items on the Emotions and Physical Problems scales) are reverse scored to correspond with the satisfaction items, where 1="very bothered" and 5="not at all bothered".[14]
Using this scale, we hope to capture whether or not patients believe they play an active role in their health and whether or not they feel empowered to alter their health status. It will hopefully also allow us to capture what barriers there are to a patient's recovery in regards to what negative feelings and limits they perceive; preventing them from making a meaningful recovery.

Perceived Function in Society: Participation Assessment with Recombined Tools-Objective
The Participation Assessment with Recombined Tools-Objective (PART-O) is an outcome scale measuring participation in the community. The PART-O consolidates questions from 3 commonly used instruments, and measures 3 domains of community participation post rehabilitation: Productivity, Out and About, and Social Relations; it is an objective measure of participation, representing functioning at the societal level. It asks questions like, *in a typical week, how many hours do you spend working for money, whether in a job or self-employed?* The PART-O was developed to examine long-term outcomes and can also be used to evaluate the effectiveness of interventions to improve social/societal functioning. The z-scores can be used to provide the basis for an assessment of progress in post-acute rehabilitation, allowing for an assessment of intra-individual differences in change across domains as well as inter-individual comparisons with the normative groups. When patients are using this tool, we will use this opportunity to ask about current employment status. [2]
We will use this tool in our study to assess to what degree do patients feel that they are able

to perform their activities of daily living. Along with how close do they believe they are to returning to premorbid level of functioning versus adjusting to their new health status.

Access to Medical Services
Tracking patient's utilization of health care services during the time of the study is an important outcome that this study hopes to measure. The aim is to see if education can ultimately reduce unnecessary access to medical care. As stated previously we hope to accomplish this by providing information to patients on red flags and when to seek medical advice. Patients will be asked to recall the number of times they have sought out medical attention since they were last seen in the subspecialty clinic. This includes walk-in clinics, hospitals, their family MD, telehealth and ER visits. Future goals after this study has been completed would be to use the ICES database to quantify the utilization of health care services in this subset patient population.

3.7.5 Retention

All subjects will be offered compensation in the form of a Tim Horton's gift card.

3.7.6 Data Management

All research data will be entered into a de-identified database and kept on a secure server at St. Michael's hospital.

3.7.7 Statistics

The IBM SPSS statistical software will be used for the data analysis. Data will be entered on demographic factors (sex, age, ethnicity, years of education), frequency and type of health care accessed will be analyzed as well. Scores on the Rivermead, PART-O and QUOLIBRI will be analyzed and comparisons will be made between the educational arm and the current standard of care group. We will be using univariate Chi-square analysis for categorical variables and 1 way analysis for continuous variables to assess for significant difference. P-value of <0.05 will be considered as statistically significant.

3.8 Ethics and dissemination

3.8.1 Ethics

If the patient is interested in this study, they will receive the consent form explaining the purpose, procedure and requirements of the project from trained research assistants who will be available to answer questions regarding the project. Informed consent will be obtained from patients who will meet the eligibility criteria and agree to participate.

If the participant cannot sign and date the consent form properly they will be asked to provide consent with an "X", their initials or by signing with their alternate hand. If the participant is completely unable to provide written consent they will be asked for verbal consent and research staff obtaining consent will document the discussion on the consent form. Initial information will be extracted from the medical record including age, medical history, imaging results, Glasgow coma scale and neurological examination. Patients who agreed to participate will be asked to complete a demographic questionnaire, the Rivermead Post Concussion Symptom Questionnaire, the QUOLIBRI and the PART-O in person for the first session and then either again in person or by telephone interview.

Participant involved in the educational arm of the study must have email and easy access to a computer. When they are randomized they will be asked for their email address. Participants will be given their study ID number when they consent. They will be asked to use this number as their ID on the survey. Follow up at 7 weeks will occur with the education arm 1 week after they have been emailed the power point material.

3.8.2 Study participants' identification

Patients will be randomly assigned a research number in a file kept separate from the data analysis file.

3.9 Appendices

1. Consent to Participate in a Research Study
2. Yellow Baseline Questionnaire: Includes Rivermead, PART-O and QUOLIBRI
3. Blue follow up Survey: Included Rivermead Post Concussion Symptoms Questionnaire (RPCSQ), PART-O and the QUOLIBRI
4. Post Concussion Headache Assessment
5. Control and Study Participant Master Lists

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