LETTER OF INFORMATION AND CONSENT TO PARTICIPATE IN A RESEARCH STUDY

St. Michael's
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Title of Research Study: Can targeted education impact the current standard of care in study participants with mild traumatic brain injury?

St. Michael's Hospital Investigators: (Available Tuesday 9:00am - 5:00pm)

Head Injury Clinic - Phone: (416) 864-5520
Research Chair: Dr. David Mazer
Principal Investigator: Donna Ouchterlony MD, Director
Co-investigators: Candice Todd MD, Neurology Resident

Research Associate: (Available Monday – Friday 9:00 am- 5:00pm)

Cindy Hunt: Phone: 416-864-6060 ext. 77081

Study Sponsor: The Head Injury Clinic – St. Michael's Hospital

INTRODUCTION

This consent form is intended for the study participant who is eligible to participate in this study. Please note, the term 'you' used in this form refers to the head injured study participant.

As a part of your care here at the Clinic, the doctor asked you a number of questions about how you have been feeling since your injury. You are being invited to participate in a research study because you have a mild traumatic brain injury.

Participating in this study is entirely voluntary. This form provides information describing the purpose, procedures, benefits, discomforts, risks if any, and precautions associated with this study. In order to decide whether you wish to participate in this research study, you should understand enough about its risks and benefits to be able to make an informed decision.

If you have any questions after you read through this form, please ask a study doctor or study staff. You may also wish to discuss your participation in this study with your doctor, family member, or close friend. If you decide to take part in the study, it is important that you are completely truthful about your health history and any medications you may be taking. This will help prevent unnecessary harm.

PURPOSE OF RESEARCH

Although most people with mild traumatic brain injury recover to their previous level of functioning, some study participants may be at risk for developing headache as a result of their head injury. Post traumatic headache is a type of headache that often starts immediately after a head injury or days later. It often resolves over days to weeks but for some study participants this

headache can persist for months or even years after injury. If you are someone who already suffered from headaches prior to your injury, this can be a new type of headache or worsening of your existing headache.

The purpose of this research study is to see if headache education helps with symptom management helps with quality of life after a mild traumatic brain injury. We also want to see how study participants are treating their headache in order to see how best to treat post traumatic headaches in the future. We may use this information in the future to develop better assessment tools and interventions for headache symptoms following traumatic brain injury.

You are being invited to participate in this research study because you have a mild traumatic brain injury and you have been identified as someone with headache symptoms. You will be placed in one of two groups:

1) mild traumatic brain injury with educational intervention
2) mild traumatic brain injury with the current standard of care.

Your participation will help to determine which symptoms or factors can affect quality of life after a traumatic brain injury.

Approximately 70 participants aged 18 to 65 will take part over a 12-week period at St. Michael's Hospital. This study is being conducted under the supervision of Dr. Donna Ouchterlony.

DESCRIPTION OF RESEARCH

Assessment Day

This study is being conducted at the Head Injury Clinic at St. Michael's Hospital. You will receive standard care as a study participant with mild traumatic brain injury, at the Head Injury Clinic. This will include a 1 to 2 hour-long assessment, at the first Clinic appointment. At this first assessment, you will be interviewed by the doctor who will ask you some questions about yourself, like your age and health. You will also complete some routine questionnaires to provide information on how you have been feeling and functioning since your injury.

If you are identified as someone experiencing a headache following your injury you will be assigned randomly either the educational intervention (PowerPoint Slides +questionnaires) or you will continue on with the current standard of care (questionnaires). If chosen to participate in the education part of the study you will be asked to review three PowerPoints that outlines 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 along with helpful lifestyle and treatment tips. Study participants will be provided with links to approved websites.

Follow-up

If you participate in the education piece of the study you will be sent a PowerPoint presentation 6 weeks from your initial clinic visit that you have a week to review. Someone from the clinic will

contact you a week later to ensure that you can open the PowerPoint. At the 12-week time point, you will be sent another PowerPoint that will cover other topics in headache. Once again you will be contacted and you will complete a follow up survey consisting of a general health questionnaire, a health status survey and headache symptom survey along with a quality of life assessment and a return to work/school status checklist, with you over the phone, online or in person if you are scheduled in the clinic for follow up. Those not participating in the education piece of the study will be asked to fill out the same follow up survey at this time point as well.

Each PowerPoint should take 10-20 minutes to review but you are free to review to the PowerPoint as many times as you need. The 12-week follow up with consist of the PowerPoint along with a telephone survey, which should take approximately 30 minutes to complete.

By participating in this study, you will be consenting to the collection of the assessment and information regarding your treatment for your injury at the Head Injury Clinic. We are also requesting permission to review your medical chart so that we can record information about your traumatic brain injury such as the date and cause of your injury; and which medications you are taking.

If you agree to participate in the study, you will be asked to sign this consent form at which point you will be entered into the study. This will take approximately 10 minutes on the day of your initial visit to the clinician's office.

Study Group	Timeline	Assessments and Interventions		
		Baseline Study Participant Questionnaire Survey	PowerPoint Presentation	Visit Follow- up Questionnaire
Mild Traumatic Brain Injury Education Group	Initial Visit (Week 0)	x	x	
	Week 6 PowerPoint presentation is emailed		x	
	Week 7 Follow up			x
	Week 12 PowerPoint presentation emailed		x	
	Week 13 Follow up			x
Mild Traumatic Brain Injury Current standard of care	Initial Visit (Week 0)	x		
	Week 13 Follow up			x

ADDITIONAL FOLLOW-UP QUESTIONNAIRES BY TELEPHONE:
If you are scheduled for follow-up appointments at the Clinic, but then decide not to attend, we are asking that the study personnel may contact you to complete questionnaires for the missed follow-up over the phone. With your consent, the study personnel will complete a follow up questionnaire either over the phone or via online survey.

POTENTIAL HARMS
Due to your symptoms it may be difficult to look at a screen for a prolonged period of time. Or during the survey portion you may feel fatigue. You can look at the PowerPoint at a time that is most convenient for you or choose not to respond to a question on a survey.

POTENTIAL BENEFITS
You may not receive any direct benefits from participating in this study, other than the usual standard of care that you will be receiving for the treatment of your symptoms following traumatic brain injury. However, the results of the study may lead to better assessment tools and/or treatments for study participants with headache following mild traumatic brain injury.

TREATMENT OPTIONS
Participating in this study will in no way alter your care at the Clinic. If the Clinic doctor refers you for further treatment or therapies you should follow through with the referral. The follow-up telephone calls or study assessments are not substitutes for the referred treatments/therapies.

CONFIDENTIALITY AND PRIVACY
The study investigators, coordinators, nurses and delegates (hereby referred to as "study personnel") are committed to respecting your privacy. No other persons will have access to your personal health information or identifying information without your consent, unless required by law. Any medical records, documentation, laboratory samples, or information related to you will be coded by study numbers to ensure that persons outside of the study (i.e., sponsors) will not be able to identify you. All information that identifies you will be kept confidential and stored and locked in a secure place that only the study personnel will have access to. In addition, electronic files will be stored on a secure hospital or institutional network and will be password protected. No identifying information about you will be allowed off site in any form. Examples include your medical chart, copies of any part of your chart or any notes made from your chart. It is important to understand that despite these protections being in place, experience in similar studies indicates that there is the risk of unintentional release of information. The principal investigator will protect your records and keep all the information in your study file confidential to the greatest extent possible. The chance that this information will accidentally be given to someone else is small.
By signing this form, you are authorizing access to your medical records by the study personnel, authorized representatives of the sponsoring company, St. Michael's Hospital Research Ethics Board, and by government regulatory authorities. Such access will be used only for purposes of verifying the authenticity of the information collected for the study, without violating your confidentiality, to the extent permitted by applicable laws and regulations.

National and Provincial Data Protection regulations, including the Personal Information Protection and Electronic Documents Act (of Canada) or PIPEDA and the Personal Health Information Protection Act (PHIPA) of Ontario, protect your personal information. They also give you the right to control the use of your personal information, including personal health information, and require your written permission for your personal information (including personal health information) to be collected, used or disclosed for the purposes of this study, as described in this consent form. You have the right to review and copy your personal information. However, if you decide to be in this study or chose to withdraw from it, your right

to look at or copy your personal information related to this study will be delayed until after the research is completed.

POTENTIAL COSTS OF PARTICIPATION AND REIMBURSEMENT TO THE PARTICIPANT

We will be offering remuneration for every session that you participate in. This will be discussed with you at the time of consent.

PUBLICATION OF RESULTS

The results of this research study will be presented at various conferences, and will be published in scientific journals. Your name will not appear in any presentation or publication.

COMPENSATION FOR INJURY

If you suffer a physical injury as a direct result of participating in this study, you may obtain medical care in the same manner as you would ordinarily obtain any other medical treatment. In no way does signing this form neither waive your legal rights nor relieve the investigator, sponsor or involved institutions from their legal and professional responsibility.

PARTICIPATION AND WITHDRAWAL

Your participation in this study is entirely voluntary. If you choose not to participate, you and your family will continue to have access to customary care at St. Michael's Hospital. If you choose to participate in this study you can withdraw from the study at any time without any affect on the care you or your family will receive at St. Michael's Hospital.

If you decide to participate, any information that may affect your willingness to continue in the study will be conveyed to you in a timely manner.

However, should you decide to stop participating in the study; it will be helpful if you inform the study doctor about the decision. If you choose to withdraw from the study early, data collected up to that point may have already been used in the analyses. It is unlikely that there will be any risk/harms to you; due to the already collected data, since the data will not contain any information that identifies you personally. None of the results will be placed in your health record.

RESEARCH ETHICS BOARD CONTACT

If you have any questions regarding the rights of research participants, you can contact the chair of the Research Ethics Board, Dr. Bob Hyland, at (416) 864-6060 Ext. 2557.

FURTHER INFORMATION

If you have any further questions about the study or your participation in the study, you are welcome to contact your treating doctor or the study's supervising doctor, Dr. Donna Ouchterlony at:

Address: 30 Bond Street,
Toronto, ON M5B 1W8
Telephone: (416) 864-6060 ext. 5520

E-mail: ouchterlonyD@smh.ca

You may also contact the co-investigator, Dr. Candice Todd at:

Address: 30 Bond Street, Queen 3-082
Toronto, ON M5B 1W8
E-mail: Candice.Todd@one-mail.on.ca

CONSENT FORM FOR THE CAPABLE STUDY PARTICIPANT

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

Principal Investigator at St. Michael's Hospital: Dr. Donna Ouchterlony

I acknowledge that the research study described above has been explained to me. I have read the statements in this letter of information and confirm that the study information and procedures have been explained to me during the consent discussion. I have had the opportunity to ask questions about the study and any questions that I have asked have been answered to my satisfaction. I have been informed of the alternatives to participation in this study, including the right not to consent to participate and the right to withdraw without compromising the quality of medical care at St. Michael's Hospital for myself, or other members of my family. As well, the potential risks, harms and discomforts have been explained to me and I also understand the benefits (if any) of participating in the research study.

I understand that I have not waived my legal rights nor released the investigators, sponsors, or involved institutions from their legal and professional duties. I know that I may ask now, or in the future, any questions we have about the study or the research procedures. I have been assured that records relating to my care will be kept confidential and that no information will be released or printed that would disclose my identity without permission unless required by law. I have been given sufficient time to read and understand the above information.

I hereby consent to participate and I will be given a copy of this consent form.

_____ _____

Signature of Participant *Date/Time*

_____

Name of Participant (Please print)

_____ _____

Signature of Witness to the Consent Process (optional) *Date/Time*

_____

Name of Witness (Please print)

I confirm that I have explained the study to _____ and have supplied him/her with a signed and dated copy of the consent form:

_____ _____
Signature of Study Personnel Obtaining Consent *Date/Time*

_____
Name of Study Personnel Obtaining Consent (Please print)

Study Personnel Position: _____

I, _____, am the investigator responsible for the conduct of this study at St. Michael's Hospital and I have delegated the explanation of this study to this study participant to _____.

_____ _____
Signature of Investigator *Date/Time*

_____
Name of Investigator (Please print)

I understand that permission was given for me to participate in this study by _____ while I was too sick to make my own decisions. At this time I am now able to make my own decisions and I agree to continue to participate in this study. I will receive a copy of this consent form.

_____ _____
Signature of Participant *Date/Time*

_____
Name of Participant (Please print)

_____ _____
Signature of Witness to the Consent Process (optional) *Date/Time*

_____
Name of Witness (Please print)

I confirm that I have explained the study to _____ and have supplied him/her with a signed and dated copy of the consent form:

_____ _____

Signature of Study Personnel Obtaining Consent *Date/Time*

_____

Name of Study Personnel Obtaining Consent (Please print)

Study Personnel Position: _____