CONSENT FORM 2010W1368

**Project Investigators**:

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**Purpose: What is this study all about?**

**Purpose of the Study:**

After a mild head injury, a person may suffer from symptoms affecting vision which can dramatically challenge activities of daily living including cognitive performance. The purpose of this study is to conduct research to help compare and understand how eye exercises might improve eye function and quality of life in persons with mild traumatic brain injury (mTBI) Resulting information will help to improve rehabilitation techniques currently used to help suffers from mild head injury to recover.

Dr. Denise Gobert and Dr. Oleg Komogortsev are heading up a research team at Texas State University-San Marcos to conduct this study. You are one of 20 persons being asked to participate in this study because you have had or have not had a mild head injury within the past 12 months.

If you should have any questions regarding the research subjects’ rights or research-related injury, please feel free to ask either Dr. Gobert (Tel: 512-245-5497) or Dr. Komogortsev (Tel: 512-245-0349) for clarification. Their email addresses are dgobert@txstate.edu and [ok11@txstate.edu](mailto:ok11@txstate.edu) respectively.

Before you can decide whether or not to volunteer for this study, you must understand the purpose, any possible risks or benefits of the study, and what is expected of you. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

**Methods: What type of activities are involved in this study?**

**Testing Procedures**:

If you choose to participate in this research study, you will be asked to complete a brief 20-item intake form asking about demographic information (i.e. age, gender) , any history of head injury and any symptoms such as vision or sleep problems. You will then fill out two clinical questionnaires called the Epworth Sleepiness Scale (ESS: 8-items) and the “Dizziness Handicap Index” (DHI: 21-items) which quantify whether any symptoms such as sleepiness, dizziness, headaches, or imbalance interfere with your activities of daily living. A score of 5 or more on the ESS and a score of over 30 on the DHI indicate that your activities of daily living are being affected. You will also receive a physical screen by a physical therapist to make sure that you are able to participate safely in the study. The questionnaires and physical screen should take no longer than 30 minutes to complete and will only be administered one time.

If selected, you will participate in three (3) testing sessions (at Baseline, at 1 week and at 4-weeks) at the Neuromuscular Research Lab (Rm. #331) in the Department of Physical Therapy. Testing may also occur in the Department of Computer Sciences for data processing. Each testing session will include a computerized assessment of cognitive function and eye movement testing. Total time to perform both activities will take approximate 30 -40 minutes.

* **Cognitive Testing:**
  + After your medical screen, you will receive a cognitive assessment called the ImPact® which is a standardized, clinical assessment used for persons after suffering a head injury. The easy, computer-interaction program is used to assess your ability to remember simple words, shapes and colors over a short period of time. Test results will indicate your reaction times and the number of correct responses. This test is self-paced and will take no more than 15 - 20 minutes.
* **Eye Movement Testing:**
  + You will then be asked to sit in front of a computer screen with your head resting comfortably on a padded chin rest and look at stationary and moving targets. A device called an eye tracker will be used to collect your eye movement information. The eye tracker is similar to a web camera to record eye movement and does not cause pain or discomfort. There will be 8 - 10 activities lasting 30 seconds each. This part will last about 5 -10 minutes.
  + In addition, your dynamic vision will be assessed to see how well you can see while your head is moving. This computerized test will require that you wear a headband with a lightweight sensor attached to it while you sit in front of a computer screen. You will be asked to move your head and tell what direction the letters are oriented on the computer screen. Your dynamic vision score will be compared to your vision when your head is not moving. This second part will last about 10 minutes.
  + This eye movement testing will take no more than 20 minutes.

**Time Commitment: How much of my time will be involved with this study?**

**Total Time Commitment to Study:**

Your commitment to this study will include three (3) test sessions (Baseline, at 1 week & at 4-weeks follow-up) including completion of the standardized questionnaires, the cognitive assessments and the eye assessment activities. The first session will be longer because of the consent form, physical screen and questionnaires which will take about 30 minutes. The cognitive and eye exercise sessions will last 30-40 minutes each (Total= 3 sessions). Therefore your total participation will be approximately 2.5 – 3.0 hours over approximately four (4) weeks.

**Risks: What the risks involved in this study?**

**Discomforts and Risks:**

There are only minimal discomforts and risks associated with this study. Although it is rare, you may experience slight fatigue or muscle soreness initially after performing some of the fatigue or dizziness, vertigo, headaches, eye fatigue while performing the eye movement activities. The activity will be stopped immediately and rest breaks will be provided as needed if you do experience any of these symptoms. These symptoms usually decrease over time as you become better at each exercise. In addition, you may ask to stop any test or exercise at any time if you feel that the activities are too uncomfortable or fatiguing without any penalty.

**Medical / Alternative Treatment:**

This project includes eye and cognitive assessment programs designed for persons with mild traumatic brain injury. Upon completion of the study, all participants will be given the opportunity to participate in the program again if study results indicate possible rehabilitation benefits. In addition, you may want to contact a physician at the Student Health Center at Texas State or a local neurologist with the Neurology Associates at 1341 Thorpe, San Marcos, Texas 78666 at 512 – 558 – 7770 for further assistance to interpret test results.

We will take all precautions to ensure your safety however, please be advised about the availability of medical treatment if a physical injury should result from the research procedures. The investigators will provide no special medical arrangements beyond calling the Emergency Services telephone number 911. Texas State University-San Marcos students may choose to be examined free of charge at the Texas State Student Health Center on campus. The investigators will report an adverse event per institutional policy. In the event you believe that you have suffered injury not immediately apparent from your participation, please contact the IRB Chairperson Dr. Jon Lasser or Ms. Becky Northcutt, IRB OSP Administrator, (Tel: 512-245-2102), who will review the matter with you, and identify any other resources that may be available to you.

**Benefits: What are the benefits involved in this study?**

**Benefits:**

Participation in this study will help you learn more about your personal thinking abilities and ability to track targets with your eyes while assisting researchers to better understand how persons with a mild head injury respond to a customized rehabilitation program. Some persons may also experience a decrease in symptoms with improved function in response to some of the special exercises. In addition, results will help develop better rehabilitation techniques for persons recovering from traumatic head injury.

**Compensation Statement**:

You will receive $10 for each session to cover time and travel even if you stop in the middle of a specific session. There are at total of three test sessions therefore a participant may be compensated up to $30.00.

**Confidentiality: Will my privacy be protected if I participate in this study?**

**Statement of Confidentiality:**

Your participation in this study is confidential. Only Dr. Gobert will have access to personal identifiers and to any information that can be associated with your identity. This information will be in a locked file cabinet in her locked office in the Department of Physical Therapy during this project and then destroyed three years after this project ends. All information that you complete will have a code number assigned rather than your name to ensure your confidentiality during any data analysis or reporting. All eye movement data and video will be stored in a locked file cabinet in a locked office in the Texas State University Computer Science Research Laboratory with Dr. Komogortsev for seven years. Results of this study may be published or presented at conferences however no personal identifying information because composite information will be disclosed.

**Questions: Who can I ask questions about this study?**

**Right to Ask Questions:**

You may ask questions about any of the research procedures by directing your questions to Dr. Denise Gobert at [dgobert@txstate.edu](mailto:dgobert@txstate.edu) or 512-245-5497 (office) or Dr. Oleb Komogortsev at [ok11@txstate.edu](mailto:ok11@txstate.edu) or 512-235-0349 (office). In addition, you may contact them if you desire for a copy of the study results.

**Request for Further Information**:

You are encouraged to discuss and/or express any concerns or questions regarding this study with the investigators at any time. You should feel confident and secure about your involvement in the study. You may also contact the Institutional Review Board (IRB) Chairperson, Dr Jon Lasser (512-245-3413 – [lasser@txstate.edu](mailto:lasser@txstate.edu)) or Ms. Becky Northcut, Compliance Specialist (512-245-2102) in the Office of Research Compliance additional information about research rights.

**Early Withdrawal: What will happen if I decide to stop participation in this study?**

**Voluntary Participation:**

Your participation is completely voluntary and you can withdraw from the study at any time without penalty or prejudice from the Department of Physical Therapy, the Department of Computer Science or any of the other departments affiliated with this study at Texas State University- San Marcos. Please notify Dr Gobert or Dr. Komogortsev or any of the authority named in this document of your intent to withdraw from the study with no adverse consequences.

**Sponsors: Who is paying for this study?**

**Disclosure and Funding:**

This project is being funded by the Research Enhancement Program at Texas State University and therefore abides by all state rules and regulations guiding state sponsored research.

In addition, the investigators involved with this project have no financial or other potential conflict of interest in performing this project. Summary findings will be provided to the participants upon request.

**Participant Consent: How do I indicate that I want to participate in this study?**

**Project Approval**:

This study has been reviewed and approved by the Texas State University’s Human Subjects Review Board.

You have been given an opportunity to ask any questions that you may have and all such questions or inquiries have been answered to your satisfaction.

You must be 18 years of age or older to consent to participate in this research study. If you consent to participate in this research study and to the terms above, please sign your name and indicate the date below.

You will be given a copy of this consent form to keep for your records.

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Participant Name (please print in all caps)

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Participant Signature Date

I, the undersigned, verify that the above informed consent procedure has been followed.

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Investigator Signature Date