Title of Study: Cognitive-Communication Screening and Early Therapy for Adults with Concussion/Mild Traumatic Brain Injury

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Type of Document: Study Protocol and Statistical Analyses

Procedures and Statistical Data Analyses: Patients with be evaluated for a concussion/mild traumatic brain injury at a local hospital in the emergency room. On the same day discharge papers, the patient will receive a description about the study and the PI contact information. During hospital follow-up phone calls to check on the status of the patients, they will be reminded of the study being conducted at the university and given the inclusionary/exclusionary criteria.

Subjects that voluntarily contact the PI and meet the inclusionary criteria will be scheduled for cognitive and communication screening at two weeks post-injury. The informed consent will be reviewed and signed prior to beginning the study. All subjects will receive monetary incentives for participation in the screening sessions.

The PI and her research assistants will audiotape all sessions to ensure that subjects' responses are scored and transcribed correctly. Inter-rater reliability of the scored items will be completed for 50% of the screenings conducted. All recordings will be destroyed one week following the sessions. The recordings will be restricted only to the PI and graduate research assistants. Next, the screening measures will be completed, and an education fact sheet will be reviewed with an emphasis on recovery.

At four weeks post-injury, the second screening session will be completed. Subjects who are below one standard deviation on screening scores will be randomly placed in either early treatment at one month post-injury or a waitlist control group which will receive the same therapy at two months post-injury. Subjects offered cognitive-communication therapy will participate in a one hour weekly session for four weeks. Prior to beginning therapy, a functional outcome measure will be administered. Intervention will consist of evidence-based therapies for working memory, executive function, and divided attention, environmental changes, and identification of problematic cognitive-communication situations. At the end of therapy, the same outcome measure will be completed.

Procedures for therapy will be the same for the waitlist control group. However, during the one month waiting period following the second screening, subjects will be given other activities that differ from the actual therapy activities.

All subjects will be contacted via phone at six months and 12 months post-injury to ensure resolution of cognitive-communication problems. If problems are identified later in recovery, the subjects will be instructed to contact their primary care physician for further referrals.

This is a longitudinal clinical study. Subjects will be followed for one year post-injury. Results from the screening measures at two and four weeks post-injury will be compared using a forward stepwise selection model procedure to determine which of the screening measures best detect persistent symptoms.

Finally, one tailed, non-paired t-tests will be used to compare pre- and post-therapy functional outcomes. Additionally, qualitative analyses will be completed on data related to the treatment.