Research Volunteers Needed

The New York TBI Model System at Mount Sinai School of Medicine is seeking people who have had a traumatic brain injury to participate in research.

The first of two studies focuses on fatigue after brain injury. We want to study how and when fatigue happens and the effects it has on the lives of people with brain injuries. In this study you will be asked to answer questions about how much fatigue you experience, your health, and your quality of life. You will also be asked to do some tests of thinking abilities, such as memory and attention, to see how fatigue affects your thinking.

The second study will evaluate the effectiveness of the drug Zoloft, an anti-depressant, in helping individuals who are depressed after brain injury. To be in this study you must be suffering from depression and be willing to try this medication for a period of 12 weeks. Participants will be randomly assigned, to receive either Zoloft or a sugar pill that contains no medicine. Then you will be asked to visit Mount Sinai every two weeks to monitor whether changes occur in your level of depression.

In each study, you will be paid for your time. You must be able to travel to Mount Sinai. If you are interested in participating in either study or both studies, please call (866) 528-7490 (a toll-free number). GCO #02-0677, IRB approved through 09/03

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The New York TBI Model System News is supported by a grant (No. H133A021918) from the National Institute on Disability and Rehabilitation Research, U.S. Department of Education, to the Department of Rehabilitation Medicine, Mount Sinai Medical Center, New York City.

If you do not wish to receive future issues of this newsletter or if you would like to be added to our e-mail list, contact us at nytbims@msnyuhealth.org or (866) 528-7490 (toll-free).

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Model System Staff

Wayne A. Gordon, Ph.D., is Project Director of the NY TBI Model System; Steven Flanagan, MD, is Project Coordinator and Medical Director of the TBI program at Mount Sinai and Elmhurst Hospital Center. At Elmhurst, Jamie Ullman, MD, is Director of Acute Care, and Jerry Weissman, MD, is Associate Director of Rehabilitation Services.

Mary Hibbard, PhD, is Director of Research, and Marcel Dijkers, PhD, is Director of National Database and Evaluation. Joshua Cantor, PhD, is Project Coordinator and Co-investigator. Teresa Ashman, PhD, is also a Co-investigator. Alexis Kramer and Sarah Schiavetti are the Research Assistants.

Within the Inpatient Brain Injury Unit at Mount Sinai, Christine Canale, RN, BSN, CRRN is the Clinical Nurse Manager. Leslie Kane, MA, OTR/L is the Therapy Manager. Lynne Kothera, PhD, is Senior Psychologist, and Dana Spivack David, MS, CCC-SLP, is an Advanced Clinician in Speech Language Pathology. Laurie Allen-Schneider, MS, PT, is the Therapy Manager for Outpatient Rehabilitation. Betty Furr, MSN, RN, CRRN, is the Director of the Rehabilitation Center at Mount Sinai. Timothy Pruce is Coordinator of Advocacy and Peer Support. In the inpatient and outpatient settings of the Model System, he serves as the initial contact for patients and families seeking information and resources on life after TBI.

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Clinical Services

The clinical program of the New York TBI Model System brings together into a coordinated effort all the elements of a ‘model’ response to TBI:

- NYC Emergency Medical Services safely remove individuals with TBI from the site of injury, provide immediate care appropriate to the injury and ensure speedy transfer to the Level I trauma center at Elmhurst Hospital Center in Queens.
- Immediate hospital care is provided at Elmhurst. Individuals with TBI admitted to Elmhurst receive comprehensive medical care provided by a wide variety of specialists, including neurosurgeons, rehabilitation physicians, a complete team of rehabilitation specialists, nurses and nursing aides.
- Inpatient medical rehabilitation services are provided either at Mount Sinai Medical Center or at Elmhurst. In both settings, specialized rehabilitation programs are tailored to the individual needs of the person, and typically include physical, occupational, speech, and neuropsychological therapies, as well as social work. Group cognitive treatment is also provided, which was developed to meet the emerging needs of individuals as they recover from injury. Support for family members is also made available.
- If needed, specialized long-term medical services are provided in two affiliated nursing homes: Park Terrace Care Center and Queens Nassau Nursing Home. In these facilities, subacute rehabilitation is provided in a well-structured setting and is monitored by physicians affiliated with the Model System.
- If needed, transitional living services may be provided at Transitions of Long Island.
- Outpatient rehabilitation is provided at Elmhurst and at Mount Sinai. Outpatient rehabilitation is often initially provided within the Phase II program, a highly structured day treatment program designed to assist individuals with TBI to readjust to community living. Social workers provide support, and physical, occupational, speech, vocational and neuropsychological therapies are provided, and often continue after successful completion of the Phase II program. Long-term outpatient rehabilitation and disability-related care are provided by Model System physicians.

Referrals to the inpatient rehabilitation service at Mount Sinai can be made by contacting the admissions coordinators at (212) 241-5417. Individuals seeking an outpatient evaluation by a neurologist may contact Alexis at (212) 241-0818.

Research Studies

Treatment of Post-TBI Depression

Infectors: Drs. Hibbard, Cantor, Flanagan, Gordon and Ashman.

Purpose: The purpose of this study is to document the efficacy of sertraline (Zoloft) in treating depression after TBI, including its impact on quality of life. Effects of sertraline on anxiety disorders, which often accompany post-TBI depression, will also be studied.

Background: Major depression is experienced more often after TBI than prior to injury. Studies have shown a high incidence even many years after TBI. Major depression is associated with poorer quality of life and social and recreational activities, reduced employment, an elevated divorce rate, reduced social and recreational activity and sexual dysfunction.

Need for Research: Of the current drug treatments for major depression, Zoloft and similar drugs (known as selective serotonin reuptake inhibitors, or SSRIs) have few side effects in people who have experienced a brain injury and have been shown to be effective in people with no brain injury. However, the effect of SSRIs on post-TBI depression has not been evaluated in a randomized, double-blinded study.

Current Research Activity: Approximately 50 men and women who are post TBI and currently depressed are being randomly assigned to a 12-week period of taking Zoloft or a placebo (i.e., a sugar pill). Over the period of study, participants will have the severity of their depressive symptoms assessed (as well as symptoms of anxiety); perceived quality of life will be measured prior to the study and at its termination. It is hypothesized that Zoloft will reduce symptoms of depression and anxiety and will increase perceived quality of life to a greater extent than the placebo.

Post-TBI Fatigue and its Treatment

Investigators: Drs. Gordon, Cantor, Dijkers and Flanagan.

Purpose: This study will be completed in two phases: Phase I will provide in-depth information about causes and consequences of fatigue; Phase II will evaluate the impact of a drug – modafinil – on post-TBI fatigue.

Background: After TBI, fatigue is one of the most common complaints, and it is associated with decreased participation in normal activities in the community and has been linked to depression.

Need for Research: Available research has failed to clarify how fatigue is triggered and the nature of its impact on people’s lives after TBI. Also, research on use of drugs to treat post-TBI fatigue is inadequate. While studies of fatigue in people with other chronic conditions suggest that modafinil helps relieve fatigue and has relatively few side effects, the use of modafinil has not yet been tested in people with TBI.

Current and Future Research Activity: In Phase I, approximately 250 individuals with TBI – across the full range of severity of fatigue, from low to high – will be recruited as study participants; 100 people with no disability who are similar to individuals in the TBI sample comprise the comparison sample. Volunteers will be interviewed and evaluated to document the effects of a demanding activity on their performance on neuropsychological tests. The relationship between fatigue and the individual’s participation in community life and their sense of well-being will be analyzed.

In Phase II, more than 100 men and women volunteers with post-TBI fatigue will be randomly assigned to a 4-week period of taking modafinil or a placebo (that is, a sugar pill). At the beginning and end of the study, the severity of fatigue and associated symptoms (for example, pain) will be assessed, as well as participation in activities and perceived quality of life. It is hypothesized that modafinil will reduce the symptoms of fatigue and will increase the person’s level of activity and perceived quality of life to a significantly greater extent than the placebo.
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Background: Major depression is experienced more often after TBI than prior to injury. Studies have shown a high incidence even many years after TBI. Major depression is on the average three to five times more common among individuals who have experienced a brain injury and have been shown to be effective in people with no brain injury. However, the effect of SSRIs on post-TBI depression has not been evaluated in a randomized, double-blinded study.

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