

RESEARCH STUDY: Adults with spinal cord injury needed to participate in a 4-week cycling program

We are looking for adults with spinal cord injury (SCI) who can participate in a 4-week cycling program . Structural and functional MRI scans of the brain and spinal cord will be used to study the effect of the cycling program.	
WHO:	Adults, age 18-99 with ASIA A-D traumatic thoracic injury without lower motor neuron involvement. To participate, you must be at least 6 months out from the injury, and be in satisfactory general health.
WHAT:	You will be asked to participate in a <u>4-week cycling program at the International</u> <u>Center for Spinal Cord Injury (ICSCI)</u> . At the beginning of the program, you will be assigned to either a Functional Electric Stimulation (FES) cycling group or a passive- cycling group. The 4-week program will consist of a total of 12 cycling sessions (3 times/week, 1 hour/session). On the day of (or on a separate day close to) your 1 st , 6 th , and 12 th cycling visit, you will also receive <u>an ASIA neurological exam, a SCIM</u> <u>functional evaluation</u> , and a <u>structural and functional magnetic resonance imaging</u> of the brain and spinal cord (total of 3 ASIA exams and 3 MRI). During the imaging, we will ask you to lie still in the MRI while we take pictures of your brain and spinal cord. The neurological exam and imaging will last approximately 60 minutes each (120 minutes total). If you have your own FES RT300 cycling bike, you will have an option to cycle at home using televisits. The screening and MRI visits will still be conducted at KKI in person.
RISKS:	The effects of magnetic fields in an MRI scanner have been extensively studied, and there are no known significant risks with an MRI exam.
BENEFITS:	There is no direct benefit to you from being in this study. This study may benefit others in the future by improving methods for the study of nervous system structure and function. If you complete the study, you will be reimbursed \$150 for participation and an additional \$60 for the cost of transportation (total of \$210; in the form of a check).
WHERE:	The International Center for Spinal Cord Injury at Kennedy Krieger Institute, The Broadway Campus (707 North Broadway, Baltimore, MD). You will have an option to perform the FES cycling in the Maple Lawn Campus (11830 West Market Place, Suite P, Fulton, MD 20759).
CONTACT:	Research Coordinator at the International Center for Spinal Cord Injury (443) 923-9235 or <u>clinicaltrials@spinalcordrecovery.org</u>



Principal Investigator: Ann S. Choe, Ph.D. Ver/Date: 3.0/07.13.2021 IRB protocol: IRB00182576