Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org)
Current SCI Clinical Trials of Rehabilitation and Technological Interventions to Improve Functional Outcomes

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Sponsor/NCT	Intervention	Inclusion/ Exclusion Criteria	Time Frames Post-SCI Follow-up	Enrollment	Study Phase Study Design	Outcome Measures	Comments
University of Ioannina NCT02031835	Body Weight Supported Treadmill Training (BWSTT) as Physical Therapy Treatment to Spinal Cord Injury Patients	8-88yr age SCI level n.s. AIS B, C, D	Time post SCI N/S F/U 6wks	Began 3/2012 Greece 50 Subjects	Phase IV Single Group Open Label	WISCI ISNCSCI Ashworth Quality of Life DXA	Effect of BWSTT on quality of life, walking capability, spasticity, functional abilities, and bone health
Hugo W. Moser Research Institute, Kennedy Krieger, Inc NCT02774603	Aquatic Locomotor Training Compared to Overground Locomotor Training in Improving Ambulatory Function and Health-Related Quality of Life	18-65yr Age C1-C7 AIS C, D Some ability to walk	Chronic SCI SCI >12m F/U 16wks	Began 6/2015 Baltimore 10 Subjects	Phase N/A RCT Parallel Group Single Blind	6 Minute Walk Berg Balance SF-36 SCI QL-23	Comparing efficacy of Aquatic vs. Over-ground locomotor training
North Norway Rehabilitation Center NCT00854555	Robotic (Lokomat) Locomotor Training vs Manual-Assisted Locomotor Training; 60 sessions over 6 months to improve walking or standing function in persons with SCI	18-70yr Age SCI level n.s. AIS C, D	Chronic SCI SCI≥2yr F/U 4wks	Began 8/2008 Oslo&Tromso Norway 60 Subjects	Phase N/A RCT Single Blind	Recovery of ability to walk/stand Improved ADL function Balance, LE strength Sensation, AIS, QoL	The ATLET Study: Robotic (Lokomat) vs Manual Assisted Locomotor Training
Instituto Nacional de Rehabilitacion NCT02749357	Robotic (Lokomat) Locomotor Training 5 sessions/wk for 6 weeks, comparing training session duration of 60 minutes vs. 30 minutes	≥16yr Age SCI level n.s. AIS C, D	Chronic SCI SCI≥6m	Not yet recruiting Mexico City 10 subjects	Phase N/A RCT Single Blind	Gait Rite System Measures Lokomat Measures SCIM III	Study comparing effectiveness of two Lokomat training session durations
Clinique Romande de Readaptation NCT02808078	Gait training on a treadmill equipped with an augmented (visual) reality system compared to standard gait training; each group receives 20 sessions of 30 minutes over the 4 week program	Age>18yr SCI level N.S. Able to walk 2 minutes	Acute/subacute SCI SCI<40days F/U 4m	Began 1/2016 Sion, Valais, Switzerland 70 Subjects	Phase N/A RCT Parallel Group Open Label	2 Minute Walk Test Berg Balance Falls Efficacy ScaleSF-36 Treadmill Kinematics	Study of added benefit of augmented reality system in persons receiving treadmill gait training
University of Manitoba NCT02554058	Device: Novel rehabilitation bike incorporating mechanical stimulators on bike pedals: studying effect on balance, walking and neurophysiology in iSCI	18-65yr Age AIS C, D Can walk 10m	Chronic SCI SCI≥12m F/U 10wks	Began 5/2015 Manitoba, Canada 10 Subjects	Phase 1 Single Group Open Label	MEP amplitude H-reflex Berg Balance 10m walk, 2 min walk WISCI Ashworth	Effects of Training With a Novel Rehabilitation Bike on the Functional Recovery and Corticospinal Plasticity
Ohio State University NCT02498548	Motor Control Training to evaluate the effect of downhill training at moderate speeds on knee function. Comparing uninjured controls vs. locomotor trained iSCI without and with knee joint rehabilitation	18-90yr Age C1-T10 AIS C, D Able to step overground & on treadmill	Chronic SCI D/C from rehab at least 6 months	Began 6/2015 Columbus, OH 32 Subjects	Phase 1/2 RCT Parallel Group Single Blind	6 minute walk test 10 meter walk test Knee power absorption Eccentric knee contraction Neuromuscular Recovery Scale Berg Balance	Eccentric Motor Control Training to Improve Human Spinal Cord Injury: Knee Function During Walking

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Ohio State University University of Notre Dame NCT02821845	Motor Control Training (3 times a week for 12 wks at slow speeds) to evaluate the effect of downhill training on hip function. Comparing uninjured controls vs. locomotor trained iSCI without and with hip joint rehabilitation	18-90yr Age C1-T10 AIS C, D Can take some steps	Chronic SCI Discharged from outpatient rehab ≥6mos	Began 6/2015 Columbus, OH 32 Subjects	Phase 1/2 RCT Parallel Group Single Blind	6 minute walk test 10 meter walk test Frontal hip loading response Neuromuscular Recovery Scale Berg Balance QoL Score	Eccentric Motor Control Training to Improve Human Spinal Cord Injury: Hip Function During Walking
University of Miami NINDS NCT02451683	Study of motor task training with real or sham stimulation assessing electrophysiological parameters of time domain and location	18-65yr Age SCI C8 & above Some grasp and reach ability	Chronic SCI SCI≥6months F/U 5months	Began 4/2015 Miami, FL 300 Subjects	Phase N/A RCT Crossover Open Label	Functional tests of arm/hand function Cortical Neurophysiology Upper limb movements scale	Study of Corticospinal Function After Spinal Cord Injury
U California Irvine NCT02473614	Use of Music Glove with sensors attached to fingertips connected to music software (e.g. guitar hero) compared to conventional hand exercise program	18-80yr Age SCI affecting arm and hand function	Chronic SCI SCI≥6 months F/U 9wks	Began 3/2015 Irvine, CA 20 Subjects	Phase N/A RCT Crossover Single Blind	Box and Block Test GRASSP	Music Glove and Conventional Hand Exercises to Patients With Spinal Cord Injuries
University of British Columbia Rick Hansen Institute NCT02799966	MyndMove, a non-invasive medical device that uses short, low energy electrical pulses with surface electrodes to cause muscle contractions which result in UE movement. By assisting movement with MyndMove stimulation, patients may gain volitional ability	Age≥18yr C4-C7 AIS B, C, D SCIM Self-Care score ≤10 No existing e-stim device	Acute-Chronic SCI Early SCI 10d-6m Late SCI>6m F/U 7wks	Not yet begun Multicenter Canada/USA 40 subjects	Phase N/A Non-randomized Parallel Assignment Open Label	SCIM GRASSP TRI-HFT ARAT	Study of the effectiveness of MyndMove therapy in improving the ability of individuals to voluntarily move their arms and hands
PXL University NCT02982811	Standard Rehabilitation Therapy together with 3X45 minute training with intelligent Activity-based Client-centered Training (iACT) device vs. Standards Rehabilitation Therapy alone during 6 week program	Age≥18yr SCI level N.S. Extrem. and/or core stability dysfunction; involvement in clinical rehab; Speaks Dutch	Chronic SCI, MS, CVA SCI≥3m	Not yet begun Overpelt, Belgium 160 Subjects (CVA, MS, and SCI)	Phase 3 Non-random Parallel Group Open Label	Wolf Motor Function Test Manual Ability Measure Modified Fatigue Impact Scale Trunk Impairment Scale SF-36 Canadian Occupational Performance Measure	Study to determine whether use of iACT device adds to benefits of Standard Rehabilitation therapy in persons with CNS impairments
Case Western Reserve University NINDS NCT02329652	Implantation and use of networked neuroprosthesis system (NNS) for arm, hand and trunk function.	Age≥17yr Motor level C4-8 AIS A, B, C, D Elbow flex≥2/5	Chronic SCI≥6m F/U 3m	Began 12/2014 Cleveland 10 Subjects	Phase N/A Single Group Open Label	ADL Abilities Test Grasp-Release Test	implanted device for providing hand function, reach, and trunk function to individuals with cervical SCI

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Case Western Reserve Univ. MetroHealth Medical Center NINDS NCT01659541	Implantation of spinal cord expiratory muscle stimulator wire leads to restore cough	18-75yr Age SCI C8 or above AIS n.s. Expiratory muscles weak	Chronic SCI AIS A: SCI≥6m AIS B, C, D ≥12m F/U 2yrs	Began 4/2015 Cleveland, OH 16 Subjects	Phase N/A Single Group Open Label	Peak Expiratory Flow Maximum Airway Pressure Caregiver Burden Inventory Secretion Management Index Incidence of Resp. Infections SCI related Quality of Life	determine efficacy of spinal cord stim, with wire leads, to produce effective cough in patients with SCI
Palo Alto Veterans Institute for Research NCT02978638	Implantation of Finetech Vocare Bladder System—a sacral nerve root stimulator. The study tests the use of the system to inhibit bladder contractions by electrically stimulating sensory nerves (as an alternative to cutting sensory nerves).	Age≥18yr SCI below C4 AIS A Dyssynergia Detrussor Hyper-reflexia	Chronic SCI SCI≥2yr F/U 12m	Began 9/2014 Palo Alto, CA 10 Subjects	Phase 1 Single Group Open Label	Bladder Capacity (Cystometry) Frequency of Incontinence	Restoration of Bladder and Bowel function using electrical stimulation and block after SCI
University of Louisville UCLA Reeve Foundation Kessler Foundation NCT02339233	Implantation and use of spinal epidural 16 electrode array for spinal cord electrical stimulation to facilitate standing and stepping in persons with SCI	18-75yr Age SCI above T10 Unable to stand or step independently	Chronic SCI SCI ≥1yr F/U 20m	Began 1/2010 Louisville 10 Subjects	Phase N/A Single Group Open Label	Voluntary Movement	Spinal Epidural Electrode Array to Facilitate Standing and Stepping After Spinal Cord Injury
Mayo Clinic NCT02592668	Implantation of a lumbar epidural stimulator. Epidural spinal cord stimulation combined with structured program of physical rehabilitation and treadmill step training	21-65yr Age SCI C7-T10 vertebral levels AIS A, B	Chronic SCI SCI≥2yr F/U 50w	Began 2/2016 Rochester, MN 2 Subjects	Phase 1 Single Group Open Label	Unassisted Sitting Time Presence of LE Volition Coordinated Treadmill Stepping Standing Wt. Bearing Time NeuroRecovery Scale	Feasibility of LE volitional movement recovery with epidural spinal cord stimulation
NeuroEnabling Technologies UCLA/Cal Tech NCT01949285	Study of transcutaneous electrical stimulation of the lumbosacral spinal cord to: 1) assess spared function following a spinal cord injury; and, 2) use this same paradigm for rehabilitation	21-65yr age C1-T12 SCI AIS A, B, C Not on ventilator or antispasticity Rx	Chronic SCI SCI≥1yr F/U 16wks	Began 6/2015 Los Angeles 24 Subjects	Phase N/A RCT Double Blind Sham control Crossover	ISNCSCI SCIM Ashworth EMG Kinematic Analysis	prototype transcutaneous stimulation device will be used to assess and rehabilitate spared spinal cord function
NeuroEnabling Technologies UCLA/Cal Tech NCT01906424	Study to determine if transcutaneous electrical stimulation of the spinal cord at 1 or 2 sites combined with training can help improve arm and hand function in people with cervical spinal cord injury	18-65yr age C1-C7 AIS C Not on ventilator or antispasticity Rx	Chronic SCI SCI≥1yr F/U 12 wks	Began 4/2016 Los Angeles 15 Subjects	Phase N/A RCT 3 groups Crossover Single Blind	ISNCSCI CUE GRASSP SCIM Ashworth ARAT	prototype device that delivers transcutaneous electrical stimulation to stimulate the cervical spinal cord.

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UCLA NCT02331979	Transcutaneous electrical and/or magnetic stimulation for spinal cord neuromodulation to improve urinary bladder function in persons with SCI	18-45yr age C2-T8 SCI AIS A, B	Chronic SCI SCI≥1yr F/U 48m	Began 9/2015 Los Angeles 24 subjects	Phase 0 Single Group Open Label	Urine Flow Voided Volume	Study of spinal cord neuromodulation to improve bladder function in subjects with SCI
UCLA NCT02313194	Study of implanted epidural electrode array for spinal cord stimulation to improved arm and hand function in subjects with non-progressive SCI above C5	Age≥18yr SCI above C5	Chronic SCI SCI≥1yr F/U 24m	Began 7/2013 Los Angeles 12 Subjects	Phase 1/2 Single Group Open Label	Assessment of Arm and Hand Function Formal Motor Testing	spinal cord stimulation to improve the ability to move in spinal cord injured humans
Vanderbilt University NCT02899858	IntraSpinal Micro-Stimulation (ISMS) with up to 16 electrodes implanted during clinically indicated spinal surgery along each side of the spinal cord at levels that correlate with hip, knee, and ankle segmental innervation.	18-50yr Age T2-T8 Undergoing surgery allowing T9-12 laminectomy AIS A	Chronic SCI SCI>1yr F/U 3yr	Began 1/2015 Nashville, TN 2 Subjects	Phase N/A Single Group Open Label	Intraoperative Movement Post-Operative Kinesiology	Microstimulation of the spinal cord for restoration of standing and walking in persons with chronic complete SCI
C. Hospitalier Univ. Vaudois Ecole Polytechnique Federale de Lausanne NCT02936453	Implanted closed-loop Epidural Electrical Stimulation (EES) combined with over-ground robot assisted rehabilitation training (STIMO) for improving ambulation in persons with chronic incomplete SCI	18-65yr Age T8 and above AIS C, D	Chronic SCI SCI≥12m F/U 9-11m	Began 7/2016 Lausanne, Switzerland 8 Subjects	Phase N/A Single Group Open Label	WISCI 10 Meter Walk, 6 Minute Walk Weight Bearing Capacity AIS, SCIM III Berg Balance, SF-36 Urodynamics, Kinematics, EMG	Single group study of the combination of closed-loop EES with robotic assisted rehabilitation in chronic iSCI
Dept. of Veterans Affairs NIH NCT01923662	Device: IST-16 (16-Channel implanted stimulator-telemeter) for standing in persons with paralysis resulting from neurological disorder such as low cervical/thoracic spinal cord injuries (C6-T12)	Age≥21yrs C6-T12 AIS N/S	Chronic SCI SCI≥6m F/U 12m	Began 4/2013 Cleveland, OH 10 Subjects	Phase N/A Single Group Open Label	Elapsed Standing Time for different stimulation paradigms Subject Impression of Stability Body Weight Distribution Standing Stability Measures	multiple-contact peripheral nerve cuff electrodes to selectively activate portions of a muscle to improve fatigue characteristics
Case Western Reserve University NIH VA Office of Research and Development NCT00623389	Device: IST-16 (16-channel implanted stimulator-telemeter) with pre- and post-surgical training to facilitate exercise, standing, stepping and/or balance in people with various degrees of paralysis	Age≥18yr C6-T12 or other paralysis AIS A, B, C Normal ROM	Chronic SCI SCI≥6m F/U 12m	Began 5/2005 Cleveland, OH 10 Subjects	Phase N/A Single Group Open Label	Standing, walking and balance performance Standing duration, reachable workspace, and ability to perform other functional activities of daily living	Evaluation of an Advanced Lower Extremity Neuroprostheses

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Case Western Reserve University VA Office of R&D NCT01474148	Device: IRS-8 (8-Channel implanted stimulator-telemeter) to facilitate stability of the trunk and hips; Study the effect of stabilizing and stiffening the trunk with FES to change the way persons with SCI sit, breathe, reach, push a wheelchair, roll in bed	Age≥21yr C4-T12 AIS A, B, C	Chronic SCI SCI≥6m F/U up to 36m	Began 7/2011 Cleveland, OH 10 Subjects	Phase 1 Single Group Open Label	Effect of Trunk stimulation on control seated posture, respiration, seated interface pressures, reach ability, seated stability & personal mobility	Surgical implantation of an 8 channel FES system to facilitate stability of the trunk and hips
American Society Of Thermalism And Climatology NCT02333695	Device: Medical Device for Magnetic Therapy. Percutaneous magnetic stimulation of the spinal cord to reverse signs and symptoms of SCI (Autonomic Dysreflexia, neurogenic bowel & bladder, spasticity, erectile dysfunction, cough impairment)	18-70yr Age Confirmed Central Nervous System Lesion SCI level n.s. AIS n.s.	Time post SCI N/S F/U 45d	Began 1/2015 Newark, NJ 50 Subjects	Phase N/A Single Group Open Label	↓ Hyperreflexia (Autonomic Dysreflexia) Stimulation of Erections, Bowel Movements, Bladder Emptying Reduced Spasticity Induced Cough	Study of the effects of spinal magnetic stimulation on Autonomic Dysreflexia, spasticity, bowel, bladder, and erection function
University of Zurich NCT02165774	Implanted Sacral Neuromodulation for improvement in Lower Urinary Tract Dysfunction (LUTD) such as urgency, frequency, incontinence, retention. Comparison of outcomes with neuromodulation turned ON vs. OFF	Age ≥18yr Neurogenic LUTD not responsive to drug therapy Level/AIS not specified	Chronic/stable neurologic injury >12m	Began 4/2012 Switzerland 60 Subjects	Phase N/A RCT Double Blind Placebo Controlled	"Successful" Neuromodulation Neuro-urological Assessments Neurophysiological Assessments Bladder/Urethra Stim Perception Thresholds Sensory Evoked Potentials	Study of bladder function/physiology outcomes with neuromodulation stimulator ON vs. OFF
University of Miami NINDS NCT02446210	Magstim 200 stimulator for Transcranial Magnetic Stimulation and electrical Peripheral Nerve Stimulation	18-65yr Age Injury above L5 Can grip bilat Can ambulate a few steps	Sub acute/Chronic SCI≥1 month F/U 5months	Began 3/2015 Miami, FL 514 Subjects	Phase N/A RCT Crossover Open Label	Motor Cortical Excitability EEG/EMG Enhanced motor UE Enhanced motor LE	Neural Control of Bilateral Hand, Arm, and Leg Movements After Spinal Cord Injury
Cleveland Clinic NCT01539109	Transcranial Direct Current Stimulation (tDCS) vs. sham tDCS in incomplete cervical SCI patients undergoing rehabilitation training	18-75yr age SCI>6m Cervical Level AIS B, C, D	Chronic SCI SCI>6m F/U 3m	Began 11/2011 Cleveland 10 Subjects	Phase N/A RCT Parallel Group Double Blind	UEMS MRI of Brain TMS	Study of tDCS combined with training of UE in incomplete tetraplegia
Shepherd Center NCT02611375	Transcranial Direct Current Stimulation (tDCS); Peripheral Nerve Somatosensory Stimulation PNSS; Sham (tDCS); each combined with functional task practice (FTP) to assess improvement in upper extremity function	18-65yr Age C1-C8 AIS A, B, C, D	Acute/Subacute, Chronic SCI SCI<6m SCI>1yr F/U 4-6wks	Began 1/2017 Atlanta, GA 70 Subjects	Phase N/A RCT Parallel Group Sham Control Double Blind	GRASSP UE Sensation (Semmes-Weinstein) Perceived UE Performance & Satisfaction (COPM)	Comparison of tDCS+FTP vs. PNSS+FTP vs. Sham tDCS+FTP to assess effect on UE function

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McMaster University NCT02351921	Transcranial Magnetic Stimulation (tMS) delivered as non-invasive "continuous theta-bust stimulation" to alter motor output to a forearm muscle and touch perception in persons with chronic incomplete SCI	18-60yr Age C4-T1 AIS B, C, D	Chronic SCI SCI>1yr F/U 30minutes	Not Begun Hamilton, Ontario 20 Subjects	Phase N/A RCT Double Blind Crossover	Motor Evoked Potential Changes Change in Forearm Muscle Force Change in Touch Perception	Repetitive Transcranial Magnetic Stimulation in Individuals With Spinal Cord Injury
University of Sao Paulo General Hospital NCT02562001	Active vs. placebo High definition transcranial electrical direct-current stimulation (tDCS) followed by robotic Lokomat BWSTT training and ARMEO Spring	18-65yr Age SCI Level n.s AIS C, D	Subacute/Chronic 1m≤SCI≤36m F/U 18wks	Not begun Sao Paulo, Brazil 20 Subjects	Phase N/A RCT Placebo Control Double Blind	WISCI AIS Ashworth Berg Balance 10Meter, 6 Minute walk SCIM	Study of tDCS on patients receiving Gait Training (Lokomat) and ARMEO Spring
University of Sao Paulo NCT02899637	Repetitive, high frequency 5Hz Transcranial Magnetic Stimulation (rTMS) over the lower limb area of the motor cortex vs. sham rTMS over 5 consecutive days of treatment	18-60yr Age SCI Level N.S. Stable iSCI; In inpatient rehab in Paraiba, Brazil	Time after SCI N.S. Must be in inpatient rehab program at study center F/U 3wks	Not begun Paraiba, Brazil 30 Subjects	Phase N/A RCT Crossover Sham Control Double Blind	AIS ASIA Motor Score ASIA Sensory Score Fugl-Meyer Electromyography	Sham controlled RCT of repetitive high frequency TMS to improve sensorimotor function in incomplete non-progressive SCI
Bronx VA Medical Center NCT02469675	Transcranial Magnetic Stimulation; median nerve stimulation; cervical transcutaneous stimulation. Combinations of magnetic and electrical stim will be compared to determine optimal effect on nerve circuits	21-65yr Age C2-C8 iSCI with ≥ 3/5 strength of finger muscles	Chronic SCI SCI≥12months F/U 90 minutes	Began 6/2015 Bronx, NY 30 Subjects	Phase N/A RCT Crossover Single Blind	MEP Hand Dexterity Grip Strength Neurophysiology	Paired Stimulation to Increase Cortical Transmission to Hand Muscles: Pilot Study
Oregon Health and Science University NCT01974635	Assisted Movement and Enhanced Sensation (AMES) Treatment for improved sensory and motor function of the UE in persons with incomplete SCI (iSCI) or brain injury, stroke.	18-65yr age iSCI sensorimotor deficit in hand/wrist	Time post SCI N/S F/U 13wks	Began 10/2013 Portland, OR 10 Subjects	Phase I/II Single Group Open Label	Joint Position Test (proprioception) Frisbee Test Box and Block Test Strength Test	25 AMES treatments over 8-13 weeks, at a rate of 2-3 sessions per week
Shepherd Center NIH NCT02340910	Various frequencies and durations of Whole Body Vibration compared to Transcutaneous Electrical Spinal Cord Stimulation for improvement in spasticity and walking in persons with motor incomplete chronic SCI	16-65 Yr Age T12 or higher AIS C, D	Chronic SCI SCI≥6m F/U 45m	Began1/2015 Atlanta 34 Subjects	Phase N/A Single Group Open Label	Spasticity (Pendulum Test) Walking Speed	Dose-Response Effects of Whole Body Vibration on Spasticity and Walking in SCI

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NCMRR NICHD NIDCD VA Office of R & D NINDS NCT00912041	Implantation of the one or two BrainGate2 sensor electrode arrays into the motor cortex; training implanted subjects to control a computer cursor and other assistive devices with their thoughts	18-75yr age Cervical SCI AIS A, B, C, D Live≤3hr drive	Time post SCI N/S F/U 1yr	Began 5/2009 4 Centers, USA 15 Subjects	Phase N/A Single Group Open Label	Safety Feasibility of BrainGate2 to establish the parameters for a larger clinical study (appropriate neural decoding algorithms, endpoints, success criteria, etc.)	4x4 mm BrainGate2 sensor is placed into the motor cortex, connected to a percutaneous pedestal.
California Institute of Technology UCLA Casa Colina NCT01958086	Implantation of two Neuroport electrode arrays in posterior parietal cortex allowing direct brain-control of a computer interface. Ultimate objective is to allow the patient autonomous control over the Google Android tablet operating system.	Age 22-65yr high cervical SCI Lives<60 miles from study center; not on ventilator	Time post SCI N/S F/U 1yr	Began 10/2013 Pomona, CA 2 subjects	Phase N/A Single Group Open Label	Subject control of tablet computer Absence of infection or irritation Adverse Events	Feasibility Study for Use of a Brain Implant for Neural Control of a Tablet Computer
University of Pittsburgh DARPA Dept. of Defense Johns Hopkins University NCT01894802	Implantation of microelectrode Cortical Recording and Stimulating (CRS) arrays in the motor cortex and sensory cortex of the brain for neural activity recording and use in control of external devices	22-70yr age Limited or no ability to use hands due to cervical SCI or other condition	Chronic Condition SCI≥1yr F/U 12m	Began 12/2013 Pittsburgh 5 Subjects	Phase N/A Single Group Open Label	Safety: array not removed for safety during 12 month F/U Efficacy: long-term recording of neural activity and successful control of external devices	Two Blackrock Microsystems CRS Arrays will be implanted in the motor cortex and sensory cortex
University of Pittsburgh Dept. of Defense Johns Hopkins University NCT01364480	Implantation of two NeuroPort electrode arrays in the motor cortex of the brain to demonstrate the safety and efficacy for long-term recording of brain activity	18-70yr age Limited or no ability to use hands due to cervical SCI or other condition	Chronic Condition SCI≥1yr F/U 12m	Began 5/2011 Pittsburgh 5 Subjects	Phase N/A Single Group Open Label	Safety: array not removed for safety during 12 month F/U Efficacy: long-term recording of neural activity and successful control of external devices	Two Blackrock Microsystems NeuroPort Arrays will be implanted in the motor cortex
University of Southern California Rancho Los Amigos NCT01964261	Implantation of 3 Neuroport electrode arrays to enable learned control of an end effector (for reach and grasp tasks) by thought augmented with sensory feedback via intracortical brain stimulation	22-65yr Age High cervical SCI AIS N/A	Time after SCI N/A F/U 1yr	Began 11/2013 California 2 Subjects	Phase N/A Single Group Open Label	Patient control of end effector (virtual or physical) Absence of Infection or Irritation	Providing Closed Loop Cortical Control of Extracorporeal Devices to Patients With Tetraplegia
Aristotle University of Thessaloniki NCT02443558	Emotiv EPOC wireless EEG headset use for control of MERCURY v2.0 robotic arms, a non-commercial 6-degree-of-freedom bimanual robotic arms device	Age≥14yrs SCI at cervical, thoracic, or lumbar levels AIS A,B,C,D,E Uninjured controls	Time after SCI N/A F/U 1yr	Not begun Greece 30 Subjects	Phase N/A Non-randomized Parallel Group Open Label	Brain Computer Interface Control SCIM III	Brainwave Control of a Wearable Robotic Arm for Rehabilitation and Neurophysiological Study in Cervical Spine Injury

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University of Miami 02564419	implant a unilateral subdural strip electrode (Resume II, Model 3587A) over the motor cortex of the brain processed in the implanted Activa PC+S connected with Bioness H200 external UE stimulator to produce hand grasp	22-50yr Age C5-6 level AIS A, B	Chronic SCI Time post-SCI N/A F/U 24m	Began 11/2015 Miami, FL 3 subjects	Phase N/A Single Group Open Label	Neurological Exams Questionnaires Functional Hand Testing AIS, motor/sensory scores SF-36	Early Feasibility Study of a Medtronic Activa PC+S System for Persons Living With Spinal Cord Injury
The Ohio State University Ali Rezai, MD NCT01997125	Neurobridge System utilizing NeuroPort electrode array implant into motor cortex coupled with external neuromuscular stimulator to produce volitional UE movement controlled by EEG activity	21-89yr age C4-C6 AIS A	Chronic SCI≥1yr F/U 9m	Began 11/2013 Ohio, USA 5 Subjects	Phase N/A Single Group Open Label	achievement of voluntary movement of the upper extremity	Neural bridge system implant and external stimulator for reanimation of UE function in tetraplegia
Rehabilitation Inst of Chicago NIH NCT01608438	Comparison of two ways of customizing the body-machine interface over 40 sessions (spread over 8 months). 1) SCI static)—the body-machine interface is static; 2) SCI Machine Learning)—there is a machine learning algorithm that adapts to the movements made by the subject	18-65yr age C3-C6 AIS A, B, C	Time post SCI N/S F/U 8m	Began 2/2013 Chicago, IL 46 Subjects	Phase N/A Non-random Parallel Group Single Blind	Time to task completion (data entry and navigation of virtual or real obstacle course) Movement Smoothness UE Strength State-Trait Anxiety Inventory	Subjects drive power wheelchairs, interact with computers through interface that maximizes effectiveness of residual motor function
New York University School of Medicine NCT02793635	15 sessions of Indego powered exoskeleton use as a gait training device for subjects with complete or incomplete paraplegia due to SCI	Age≥18yr Paraplegia AIS A, B, C, D Some LE function Height 5'1"-6'3" Weight≤250lbs	Chronic SCI SCI≥1yr F/U 3w	Began 6/2016 New York 25 subjects	Phase N/A Open Label Single Group	Functional Ambulation Category 10 Meter Walk Test 6 Minute Walk Test	Study to measure the impact of gait training with the Indego device on walking function after SCI
University of Alberta NCT02322125	Use of ReWalk Exoskeleton to train walking in individuals with chronic SCI	18-70yr Age 5'3"- 6'4" height weight≤180lbs Does not walk or Walks ≤0.4m/s SCI Level N/S AIS N/S	Chronic SCI SCI≥1yr F/U 20weeks	Began 6/2014 Alberta 15 Subjects	Phase 1 Single Group Open Label	6 minute walk test (6MW) 10 meter walk test (10MW) Manual Muscle Strength Testing Functional Ambulation Profile Balance Somatosensory Percep Threshold McGill Pain Questionnaire	characteristics of persons with SCI who most benefit from ReWalk training; feasibility of ReWalk for home/community ambulation

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James J. Peters VAMC NCT02314221	Use of ReWalk and Ekso Exoskeletons vs. Usual Activity Control Group	18-70yr Age Paraplegia T3 and below (New York) Above T2 (Maryland and New Jersey)	Chronic SCI SCI≥6m F/U 3m	Began 2/2015 New York New Jersey Maryland 64 Subjects	Phase 3 RCT Crossover Open Label	10 Meter Walk Test 6 Minute Walk Test Timed Up and Go Advanced Walking Skills Bowel Function Total Body Fat Mass (DXA)	Study of exoskeletal-assisted Walking to Improve Mobility, Bowel Function and Cardio-Metabolic Profiles in Persons With SCI
Rex Bionics NCT02417532	Study of user abilities in REX device	10-90 yr Age C4-L5 Body dimension criteria (device fit)	Time post SCI N/S F/U 2d	Began 5/2015 Australia, New Zealand, UK 100 Subjects	Phase N/A Single Group Open Label	Defined REX activity completion Transfer to REX Autonomous REX control Patient Satisfaction TUG Adverse Events	Safety and Feasibility Evaluation of Robot Assisted Physiotherapy Exercises With REX
Ekso Bionics NCT02943915	Exoskeleton Gait Training 3X/wk for 12wks vs. standard gait training 3X/wk for 12wks or no gait training/usual activity for 12wks to determine effectiveness for improving walking outcomes in participants with chronic incomplete SCI	18-75yr Age C5-T10 AIS C, D Can use Front-Wheeled Walker Amb<0.44m/sec	Chronic SCI Community-dwelling F/U 24 wks	Began 8/2016 White Plains, NY 164 Subjects	Phase N/A RCT Parallel Group Single Blind	10 Meter Walk 6 Minute Walk TUG WISCI ISNCSCI, AIS SCIM III, QoL	Ekso exoskeleton gait training vs. standard gait training vs. no gait training/usual activities for improving walking
Rehabilitation Inst of Chicago Otto Bock Healthcare Products NCT02089880	Comparison of Micro-processor Controlled Knee-Ankle-Foot Orthosis (C-Brace) vs. Stance-control Knee-Ankle-Foot Orthosis (SCO) to improve functional outcomes in individuals with lower extremity impairment	18-80yr Age LE functional impairment due to neurologic condition Prior active use of SCO or KAFO	Time post SCI N/S F/U 16wks	Began 2/2014 Chicago, IL 24 Subjects	Phase 2 RCT Crossover Open Label	6 Minute Walk 10 Meter Walk LE Muscle Strength Berg Balance Functional Gait Assessment Stair/Hill Assessment Indices	Comparing Functional Outcomes in Individuals Using Micro-processor Controlled Orthosis Versus Stance Control Orthosis
Hugo W. Moser Research Institute at Kennedy Krieger, Inc. NCT01491789	Single group study of the benefits of the VSail-Access simulator (virtual sailing simulator)	18-55y age SCI >6m SCI C1-S1 AIS A, B, C, D	Chronic SCI>6m F/U 12wks	Began 5/2011 Baltimore, MD 20 Subjects	Phase I/II Single Group Open Label	ISNCSCI SCI-QL-23 Functional Reach Grasp/Pinch Sailing Ability Questionnaire	Studying the benefits of a recreational and therapeutic program for people with SCI using the VSail-Access sailing simulator
University of Zurich NCT02149186	Interactive Computer-based Therapy System for Legs (iCTuS-L) a virtual reality (VR)-based observation, motor imagery and execution to treat lower-limb neuropathic pain and motor dysfunction	16-80yr age SCI Level N/S AIS C, D Has neuropathic pain and/or motor deficits	Acute or Chronic Acute <3m Chronic >1yr F/U 16weeks	Began 10/2009 Zurich, Switzerland 72 Subjects	Phase N/A Single Group Open Label	Questionnaires: Neuropathic Pain, Depression, ADL ,Walking Aids, Personal Assistance, Gait Transcranial Magnetic Stim Transcutaneous PN Stim	Interactive Motor Imagery in Virtual Reality

Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org)
Current SCI Clinical Trials of Rehabilitation and Technological Interventions to Improve Functional Outcomes

December 5, 2016

This table is abstracted from the clinical trial registration website www.clinicaltrials.gov using the search term "Spinal Cord Injury" and is updated periodically. This table was derived from a www.clinicaltrials.gov search on December 5, 2016 which found a total of 831 SCI trials. Of these, 271 trials were listed having known status and as currently recruiting or not yet recruiting. The table includes 54 SCI trials from the search that: 1) are currently actively recruiting or soon-to-be recruiting subjects; 2) are interventional (testing an intervention/treatment) using rehabilitation, neural stimulation and/or assistive technology strategies and 3) targeted improvement in neurological impairment or related activities outcomes.

Interventional clinical trials are routinely registered on www.clinicaltrials.gov based on legal requirements* and because scientific journals may require registration for publication of the trial results. Investigators may choose not to register some early phase trials and those testing behavioral interventions, even though they may be important and scientifically rigorous studies.

***U.S. Public Law 110-85 requires the registration and reporting of results of "certain applicable clinical trials," i.e., controlled interventional clinical trials that are subject to FDA regulation and that involve a Drug or Biologic (other than Phase I investigations), or Device (other than small feasibility studies); http://prsinfo.clinicaltrials.gov/fdaaa.html.**

Terms/Abbreviations

NCT number: all trials registered with www.clinicaltrials.gov are assigned a registration number that begins with NCT (e.g. NCT01321333). The number listed for the trials in the table can be used in the search field to access the webpage describing the trial, the study centers, and contact information in more detail.

Phase of Study: Clinical trials usually progress in phases from 1 to 4; Note: trials of rehabilitation and technology interventions are commonly not classified by Phase of Study; i.e. not applicable (N/A) or not specified (N/S)—sometimes documented by investigators as Phase 0

1. **Phase 1 trials are usually first-in-human or first-in-disease/condition experiments that are intended to demonstrate feasibility (can it be done), safety (is it reasonably safe), and tolerability (are the side effects tolerable). Phase 1 trials usually do not include a comparison control group and as such, do not provide direct evidence of the interventions efficacy. Phase 1 trials usually enroll a small number of subjects and are commonly done at a single study center but may use a small number of collaborating centers.**
2. **Phase 2 trials follow successful completion of Phase 1. Phase 2 trials are used to develop information on intervention administration (how to give), dose (how much to give), timing (when and how long to give), effect of the intervention on the body (what does it do, beneficial or harmful). Phase 2 trials commonly utilize multiple study centers, many subjects, and include a randomized control group to provide direct information about efficacy and safety of the intervention. Phase 2 trials enable refinement of how to administer the intervention and how to measure its beneficial effects (what Outcome Measurement to use).**
3. **Phase 3 trials are conducted using the refined protocols developed from Phase 2 trials. Phase 3 trials are often termed "pivotal" studies because they are sufficiently well-designed and rigorously conducted that their results, if positive, can be used to make the case for regulatory approval (e.g. trials that lead to FDA approval for clinical use). Phase 3 trials almost always enroll large numbers of subjects (in the hundreds or more), use multiple study centers, and randomized control group design (with placebo control and double blinding if feasible). The FDA generally requires two successful confirmatory Phase 3 trials of an intervention for approval.**
4. **Phase 4 trials are conducted after regulatory (e.g. FDA) approval to gather additional safety and efficacy data.**

Open Label: a trial in which there is no attempt to conceal the identity of the intervention from the subjects; i.e. there is no "blinding" or "masking" of the intervention—the subjects know that they are receiving the "active ingredient" rather than a placebo.

RCT: Randomized Controlled Trial—a clinical trial in which subjects are randomly (like flipping a coin) assigned to either receive the active treatment or an alternative (control). Well-designed RCT's minimize the influence of variables other than the intervention that might have an effect on the desired outcome. For this reason, they provide the best evidence of efficacy and safety. The most rigorous RCT's utilize a placebo (inactive) control group and blinding (concealing active vs. control assignment) to minimize bias in the interpretation of study results.

F/U: follow-up

N/A: not applicable

N/S: not specified

ISNCSCI: International Standards for Neurological Classification of Spinal Cord Injury—sometimes referred to as the ASIA (American Spinal Injury Association) standards. This refers to the accepted international standards for performing motor/sensory physical examination of persons with spinal cord injury and the classification scheme for documenting the neurological level and the severity (completeness) of injury.

AIS: the ASIA (American Spinal Injury Association) Impairment Scale is a component of the ISNCSCI that classifies the degree of motor/sensory sparing below the level of injury. The AIS scale ranges from A (most severe, complete injury with no sparing of sensory/motor function in the sacral segments S4-S5 that innervate the anus/rectum) to E (normal). AIS B describes sensory only sparing; AIS C describes sensory and very weak motor sparing; AIS D describes sensory and stronger but not normal motor sparing.

Ashworth: an ordinal measurement scale used to rate the severity of spasticity

Barthel Index: is an ordinal scale used to measure performance in activities of daily living (ADL).

Berg Balance Scale: A 14-item objective measure designed to assess static balance and fall risk

Frankel Scale: an older scale for classifying severity of injury that was modified in 1992 to create the AIS.

SCIM: the Spinal Cord Independence Measure is a measure of a person's ability to perform certain activities independently; i.e. an outcome measure of a research subject's independence in the performance of a variety of specific activities.

EMG: the electromyogram refers to a physiological test of muscle and nerve function.

GRASSP: Graded Redefined Assessment of Strength, Sensibility, and Prehension is a clinical measurement of upper limb function for use in person with tetraplegia (quadriplegia)

H-Reflex: an electrophysiological measure that assesses the monosynaptic reflex; used as a measure of reflex pathway continuity and excitability

CUE: Capabilities of Upper Extremity is a clinical measurement of upper limb function for use in person with tetraplegia (quadriplegia)

ARAT: Action Research Arm Test is a clinical measurement of upper limb function

TRI-HFT: Toronto Rehabilitation Institute Hand Function Test, a clinical measure of hand function

WMFT: Wolf Motor Function Test

Wernig Scale: a 6-item (0–5) classification scheme that describes the degree of walking independence with or without ambulatory aids.

FMA-UL: Fugl-Meyer Assessment - Upper Limb

ICSH: International Classification for Surgery of the Hand in Tetraplegia is a clinical measure of hand function used by surgeons performing reconstructive surgery to improve function in persons with tetraplegia

DASH: Disability of Arm, Shoulder, Hand scale is a measure of the upper limb function

DXA: Dual-energy X-ray absorptiometry is a test which measures bone mineral density

tDCS: Transcranial Direct Current Stimulation

MEP: Motor Evoked Potentials

10 Meter Walk Test: the time required to walk 10 meters

6 Minute Walk Test: the distance that can be walked in 6 minutes

WISCI: Walking Index for Spinal Cord Injury is an ordinal scale measure for walking capabilities in persons with spinal cord injury

PIADS: the Psychosocial Impact of Assistive Device Scale (PIADS) is a 26-item, self-report questionnaire designed to assess the effects of an assistive device on functional independence, well-being, and quality of life.

PGI: Patient Global Impression is a patient reported outcome measurement that rates symptom severity, treatment response, or other specified outcomes on a multipoint scale