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 NS AIS B, C, D	Time post SCI NS F/U 6wks	Began 3/2012 Greece 50 Subjects	Phase N/A 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 NS 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 NS AIS C, D	Chronic SCI SCI≥6m	Began 8/2017 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 NS 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
Indiana University NCT03144388	High intensity stepping training in multiple environments, including overground, on a treadmill and on stairs vs. High intensity non-stepping training, including balance, strength, and cycling tasks. 20 sessions over a 6 week period	Age 18-75yr SCI C1-T10 AIS C, D Can walk without assistance	Chronic SCI SCI≥1yr F/U 6wks	Began 7/2017 Indiana 20 Subjects	Phase N/A RCT Parallel Group Crossover Option Single Blind	Walking Speed Walking Distance	Study of the effects of rehab activity task-specificity on locomotor recovery in persons with chronic SCI
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 F/U 16wks	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

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Khon Kaen University NCT03254797	Stepping task training with- vs. without external feedback of weight loading on the training leg for 20 minute sessions, followed by 10 minutes of overground walking (session duration 30 minutes); 5 sessions/wk X 4 weeks	Age≥18yrs SCI level NS AIS NS (iSCI) Independent Ambulation without devices	Time post-SCI NS F/U 7mos	Began 4/2017 Thailand 17 Subjects	Phase N/A RCT Parallel Group Single Blind	10 meter walk test TUG 6 minute walk test LE Strength (5X Sit-to-Stand)	Studying whether step training with weight loading feedback will improve ambulatory function in patient with iSCI
University of Louisville NCT03036527	Studying the effects of activity-based locomotor, activity-based standing, and activity-based upper extremity ergometry training on recovery of bladder and sexual function. One hour training sessions, 5 days/wk for 80 sessions.	Age≥18yr SCI level NS (suprasacral) AIS NS Spinal Shock resolved	Chronic SCI Inpatient rehab completed F/U 5 years	Began 9/2014 Louisville, KY 30 Subjects	Non-random Parallel Group Open Label	Bladder Capacity Voiding Efficiency (% voided) Leak Point Pressure Bladder Compliance IIEF, FSFI	Effects of Activity Dependent Plasticity on Recovery of Bladder and Sexual Function After SCI
Hospices Civils de Lyon NCT03190863	Effect of Motor Imagery (MI) with neurofeedback vs. MI alone vs. Sham MI for improving grasp function in subjects with C6-7 AIS A or B SCI; three 45min sessions/wk X5 wks.	Age 18-55yr SCI level C6-7 AIS	Chronic SCI SCI>6mos F/U 19wks	Began 10/2017 France 21 Subjects	Phase N/A RCT Parallel Group Single Blind	3D Motion analysis of grasp activities ROM Muscle strength testing Box & Block, 9 hole peg QIF	effect of motor imagery with or without visual neurofeedback on grasping capabilities after C6-C7 SCI
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
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	Began 10/2017 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
MyndTec Inc. US Dept of Defense NCT03439319	MyndMove® therapy, a non-invasive FES technique using surface electrodes to stimulate 3-8 muscles to produce purposeful movement in the arms/hands, compared to conventional rehabilitation therapy	Age≥18yrs SCI C4-C7 AIS B, C, D SCIM-SC≤10	Chronic SCI 4m<SCI<12m F/U 24wks	Not yet begun Multicenter Canada/USA 60 subjects	Phase N/A RCT Parallel Group Single Blind	SCIM-Self Care (SCIM-SC) GRASSP TR-HFT ARAT Ashworth SCI-QOL	comparing electrical neuromodulation delivered by MyndMove® therapy to intensive upper-limb conventional therapy

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Northwell Health NCT03385005	Up to 4 sessions weekly for up to 8 weeks of transcutaneous electrical stimulation on the forearm using an investigational neuromuscular stimulator in order to evoke different hand and finger movements	Age 18-65yrs C5 motor level No volition C6-T1 segments AIS A	Chronic SCI SCI ≥1yr F/U 8wks	Began 9/2017 New York 15 subjects: 3-10 healthy volunteers; 2-5 subjects with SCI	Phase 1 Sequential Assignment Open Label	Refined Hand Movement Force Measurement of Wrist & Finger Movement	Evaluating Neuromuscular Stimulation for Restoring Hand Movements
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 NS 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 FDA OOPD 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
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 NS 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 N/A Single Group Open Label	Bladder Capacity (Cystometry) Frequency of Incontinence	Restoration of Bladder and Bowel function using electrical stimulation and block after SCI

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Swiss Paraplegic Centre Nottwill NCT03048331	Surface Functional Electrical Stimulation (FES) in persons who have had Upper Extremity reconstructive surgery (tendon and/or nerve transfers) to determine if the additional of FES vs. standard therapy can improve motor learning and functional outcomes after these surgeries	Age≥18yr SCI C4-T1 AIS A, B, C, D Planned UE reconstructive surgery	Chronic SCI SCI>6m F/U 16wk	Began 3/2017 Switzerland 30 Subjects	Phase N/A RCT Parallel Group Open Label	Force, Power of treated muscle COPM Surface EMG Treatment Effectiveness (Questionnaire) Ultrasound (Muscle Volume)	Pilot Study of FES in in persons with tetraplegia who receive UE reconstructive surgery
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 receiving locomotor training.	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
University of Louisville NCT03364660	Spinal Cord Epidural Stimulation utilizing stim parameters for voluntary movement, standing, or cardiovascular responses combined with leg movement training or stand training while sitting or supine.	Age≥18yrs SCI level NS Unable to move legs/stand	Chronic SCI SCI≥2yrs F/U 20m	Began 11/2017 Louisville 36 subjects	Phase N/A RCT Parallel Group Open Label	Cardiovascular Assessments Functional Movement Assessments Standing Assessments	Task & Physiological Specific Stimulation for Recovery of Autonomic Function, Voluntary Movement, and Standing
U of Minnesota NCT03026816	Implanted epidural spinal cord stimulator for improving volitional motor activity autonomic function in persons with chronic motor complete SCI; comparing outcomes with stimulator on vs. off (sham stimulation).	Age≥22yr SCI C6-T10 AIS A, B	Chronic SCI SCI>1yr F/U 15m	Began 8/2017 Minneapolis 100 Subjects	Phase N/A Single Group Single Blinded Outcome (BMCA)	Brain Motor Control Assessment Volitional Movement Sympathetic Skin Response Blood Pressure Cerebral Blood Flow (tilt table) Arterial Stiffness	Optimization of Epidural Stimulation parameters for Chronic Motor Complete SCI
Shirley Ryan AbilityLab NCT02991248	Three arm study comparing robotic/pelvic force-perturbation treadmill training with 1) active vs. 2) sham transcutaneous spinal direct current stimulation (tsDCS), and 3) standard treadmill training only. Three treatment sessions per week for 6 weeks.	18-65yr Age SCI C4-T10 AIS C, D Able to walk 10 meter with no more than AFO	Time after SCI NS F/U 14wk	Not yet begun Chicago 54 subjects	Phase N/A RCT Parallel Group Single Blind Assessments	Gait Speed (overground) 6 minute walk test Dynamic Gait Index Berg Balance Scale	whether pelvis perturbation training with tsDCS will be effective in improving dynamic balance and locomotor function
University of Zurich NCT03137108	Transcutaneous electrical spinal cord stimulation (tSCS) using RehaMove 3 stimulator applied during standing and overground walking in FLOAT body-weight support system. 2 sessions within 2 weeks.	Age≥18yr SCI above T12 AIS C, D Can walk 10 m independently	Subacute SCI 3-12m Chronic SCI≥12m F/U 2 wks	Began 10/2017 Zurich, Switzerland 15 subjects	Phase N/A Single Group Open Label	Kinematic Movement Motion Capture Force Plate	effects of tSCS with different stimulation modalities on voluntary motor in persons with iSCI

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Hugo Moser Research Inst. Kennedy Krieger, Inc. NCT03384017	Transcutaneous Spinal Cord Stimulation (TSCS) via skin surface electrodes. Subjects will participate in 24 two hour sessions with 30 minutes of TSCS and strengthening, task practice and gait-based therapy—gait training will continue after TSCS.	Age 18-65yrs SCU above T10 AIS NS	Chronic SCI SCI>1yr F/U 8wks	Began 1/2017 Baltimore 10 Subjects	Phase N/A Single Group Single Blind	10MWT TUG WISCI II 6MWT	Impact of TSCS & Gait Training on Walking Function in Patients With SCI
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
University of Louisville NCT03452007	Epidural Spinal Cord Stimulation with 16 electrode array allowing determination of stimulation parameters and electrode configurations that result in improved bladder capacity and voiding efficiency	Age>18yrs Have implanted stimulator SCI above sacral segments AIS A, B	Chronic SCI SCI>2yrs F/U 2yrs	Not yet Begun Louisville 6 subjects	Phase N/A Single Group Open Label	Urodynamics Bladder Capacity Detrusor Pressure Voiding Efficiency	Functional Mapping With Lumbosacral Epidural Stimulation for Restoration of Bladder Function After SCI
Shepherd Center NCT03240601	30 minute sessions of Active vs. Sham comparator Transcutaneous Spinal Cord Stimulation (tcSCS) for reducing spasticity and improving walking function in participants receiving locomotor training	18-65yr Age SCI T11 or above Able to take a step with or without assistive device; has spasticity in LE	Chronic SCI Discharged from inpatient rehab	Began 7/2017 Atlanta, GA 28 subjects	Phase N/A RCT Parallel Group Triple Blind	Pendulum/Leg Drop Test 10 meter walk test 2 minute walk test Ankle Clonus/foot drop test Other assessments of spasticity Borg Perceived Exertion	Combined Influence of Transcutaneous Spinal Cord Stimulation and Locomotor Training on Spasticity and Walking Outcomes
U of Washington NCT03184792	Upper extremity rehabilitation exercise therapy with- or without transcutaneous spinal cord stimulation	21-70yr Age SCI Level C7 or higher Impaired hand function	Chronic SCI SCI≥1yr F/U 6m	Began 12/2016 Seattle, WA 10 Subjects	Phase N/A RCT Open Label Crossover	GRASSP, ISNCSCI SCIM Spasm Score Grip & Pinch Strength Pain Rating Scale SSEP, MEP	Transcutaneous Electrical Spinal Stimulation to Restore Upper Extremity Functions in 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

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Vanderbilt University Med Ctr 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 T10 and above AIS C, D Can stand with walker/crutches	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 NS	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
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 N/A 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
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

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VA Office of R&D University of Miami NCT03447509	Transcranial non-invasive Magnetic Stimulation (iTMS) (vs. sham iTMS) with acoustic startle during performance of UE movement tasks/training	Age 18-85yrs SCI above L5 AIS A, B, C, D Visible grip/UE movement ability	Chronic SCI SCI>2m F/U 60minutes	Not yet Begun Miami 300 Subjects	Phase N/A RCT Crossover Single Blind (subject)	Motor Evoked Potential Amplitude Grip Strength 9-Hole Peg Test	Testing the effects of iTMS protocol on grasping function after SCI
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 NCT03237234	Upright (standing) motor skills training with- or without (sham) transcranial (via scalp electrodes) direct current stimulation (tDCS) of the motor cortex of the brain, to improve walking function. Three 25-30 minute training sessions; baseline and follow-up assessments sessions.	18-65yr Age C3-T10 level AIS C, D Stand 5min Takes 3 steps	Chronic SCI SCI≥12m F/U 5 days	Began 3/2017 Atlanta, GA 35 subjects	Phase N/A RCT Parallel Group Sham Control Double Blind	10MWT, 2MWT Ankle Dorsiflexion Strength Gait Kinematics Berg Balance Scale Falls Efficacy Scale 5 times sit-to-stand SCATSR	Study of tDCS for enhancing corticospinal tract activation to improve walking function
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
Shepherd Center NCT03237091	Bi- or Unihemispheric, transcranial pulsed (tPCS) or direct (tDCS) current stimulation, vs. sham stimulation (5 different interventions). 30 minute sessions. Subjects will receive a single session of each intervention.	18-65yr Age C1-C8 Level AIS A, B, C, D Some UE impair Thumb or index volition	Time after SCI NS F/U 5 wks	Not yet begun Atlanta, GA 19 subjects	Phase N/A RCT Crossover Double Blind Sham Control	Motor control and strength Corticospinal Excitability (MEP) Stimulation Questionnaire	Various modes of transcranial stimulation to improve functional recovery
University of Sao Paulo General Hospital NCT02562001	Active vs. placebo High definition transcranial electrical direct-current stimulation (tDCS) followed by robotic Lokomat BWSTT training. Inpatients 5 sessions/wk X 6wks; Outpatients 3 sessions/wk X 10 wks	18-65yr Age SCI Level NS AIS C, D	Subacute/Chronic 1m≤SCI≤36m F/U 18wks	Began 11/2015 Sao Paulo, Brazil 42 Subjects	Phase N/A RCT Placebo Control Double Blind	WISCI AIS Ashworth Berg Balance 10Meter, 6 Minute walk SCIM	RCT of the effects of tDCS on patients receiving robotic Gait Training (Lokomat)

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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 NS 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≥12 months F/U 90 minutes	Began 6/2015 Bronx, NY 30 Subjects	Phase N/A RCT Crossover Open Label	MEP Hand Dexterity Grip Strength Neurophysiology	Paired Stimulation to Increase Cortical Transmission to Hand Muscles: Pilot Study
Universidade Federal de Pernambuco NCT03394560	12 sessions of active or sham repetitive transcranial magnetic stimulation (rTMS) combined with Body Weight Supported Treadmill Training (BWSTT)	Age 18-55yrs SCI below T1 AIS C, D Not community walker	Chronic SCI SCI>8 months F/U 2 months	Not yet Begun Brazil 20 Subjects	Phase 2 RCT Parallel Group Double Blind	WISCI II AIS, LEMS SCIM III Ashworth SF-36	rTMS & BWSTT for sensory motor recovery in persons with chronic incomplete SCI
University of Zurich NCT03053791	Unilateral implantation of a Medtronic Activa SC deep brain stimulation system in the mesencephalic locomotor region	18-75yr Age SCI T10 & above AIS C, D walk 10 meters	Chronic SCI SCI≥6m F/U 6m	Began 2/2017 Zurich, Switzerland 5 Subjects	Phase 1/2 Single Group Open Label	6 Minute Walk TUG, Ashworth SCIM III WISCI II SF-36 Bladder, Bowel, Sexual Function	Mesencephalic locomotor region deep brain stimulation for improvement of locomotion and gait
University of Nove de Julho NCT03031223	3 sessions/wk X 4 wks of Low Level Laser Therapy (LLLT) administered transcutaneously to the injury site at a wavelength of 808 nm using a Twin Flex Evolution diode laser vs. no LLLT control	Age NS SCI C3-L5 AIS B, C, D	Acute-Chronic SCI SCI≤1yr F/U 90d	Began 8/2016 Sao Paulo, Brazil 30 Subjects	Phase N/A RCT Parallel Group No Blind	EMG	Evaluation of Sensory-motor Response to Low-level Laser Therapy for the Treatment of SCI
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	16-70 Yr Age T12 or higher AIS C, D	Chronic SCI SCI≥6m F/U 45m	Began 1/2015 Atlanta 57 Subjects	Phase N/A Single Group Open Label	Spasticity (Pendulum Test, SCI-SET, Electrophysiology) Walking Speed, Endurance, Pattern Strength, Pain	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 NS 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 NS 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 NS	Time after SCI NS 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
University of Miami NCT02564419	Implantion of a unilateral subdural strip electrode (Resume II, Model 3587A) over the motor cortex of the brain processed in an implanted Medtronic Activa PC+S connected with Bioness H200 external UE stimulator to produce hand grasp. 24 training sessions over 3-6 months	22-50yr Age C5-6 level AIS A, B	Chronic SCI Time post-SCI NS 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

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The Ohio State University Marcia Bockbrader, 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
University of Glasgow NCT01852279	BCI controlled FES vs. passive therapist controlled FES for improved hand therapy outcomes	18-70 yr Age C4-8 level AIS B, C	Subacute/Chronic Time post-SCI NS	Began 5/2013 20 Subjects Glasgow, UK	Phase N/A RCT Parallel Group Double Blind	Manual Muscle Strength ROM EEG analysis SSEP QIF Questionnaire	BCI control of FES for Hand Therapy in Spinal Cord Injury
Shirley Ryan AbilityLab 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 NS 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
Parker Hannifin Corp. 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 3wks	Began 6/2016 New York, Texas, Virginia 10 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
Vanderbilt University NCT03082898	Indego Exoskeleton walking: three 90minute walking sessions per week for 8 weeks (24 sessions).	Age≥18yr SCI C5 or lower AIS A, B, C, D Non- or Poorly ambulatory FIM gait 1-6	Chronic SCI SCI≥6mos F/U 18wks	Began 11/2016 Tennessee, Florida, Minnesota 24 Subjects	Phase N/A Open Label Parallel Group AIS A, B AIS C, D	10 Meter Walk Test 6 Minute Walk Test WISCI-II FIM Gait Score TUG ISNCSCI Self-Report Score	Study of exoskeletal walking effects on functional, neurological, and health outcomes

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Kessler Institute Kessler Foundation NCT03096197	Transcutaneous lumbosacral stimulation (TLS) with Exoskeleton Assisted Walking (EAW) compared to EAW alone for recovery of walking. Each group receives 80 sessions of treatment (60 minutes of EAW+TLS or EAW alone, with EAW+TLS group also receiving 15 minutes of overground training without EAW.	Age 21-58yrs SCI C6-T10 AIS C, D LEMS≥16 Non-walking Wheelchair user	Chronic SCI SCI>6yrs F/U 28wks	Began 03/2017 New Jersey 24 Subjects	Phase N/A RCT Open Label	6 minute walk test (6MW) 10 meter walk test (10MW) Berg Balance Scale LEMS	Study of the effect of adding TLS to EAW on walking recovery in persons with chronic non-ambulatory incomplete SCI
University of Alberta NCT02322125	Use of ReWalk Exoskeleton to train walking in individuals with chronic SCI. Intensive exoskeleton training 1.5hr/day, 4 days/wk for 12- 14 weeks (approx. 50 sessions).	18-70yr Age 5'3"- 6'4" height weight≤180 lbs Does not walk or Walks ≤0.4m/s SCI Level NS AIS NS	Chronic SCI SCI≥1yr F/U 20weeks	Began 6/2014 Alberta 15 Subjects	PhaseN/A 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
University of Calgary NCT03144830	Indoor, overground walking program using an exoskeleton wearable walking device under the supervision of a physiotherapist. 90 minute sessions, 2-3 times weekly for 8 weeks.	Age≥15yrs C7 and below AIS A, B, C, D Stable spine Adequate ROM	Acute/Subacute SCI SCI<6mos F/U 2 m	Began 6/2016 Calgary, CA 10 Subjects	Phase N/A Single Group Open Label	Cardiorespiratory Status Orthostatic BP & HR Responses 10MWT 6MWT Perceived Extertion Falls VAS Pain Scale	Studying safety and feasibility of using an exoskeleton in subjects who are less than 6 months post SCI
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 N/A 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
Ekso Bionics Burke Med. Res. Inst. NCT02943915	Exoskeleton Gait Training 3X/wk for 12wks vs. standard BWSTT 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 Multicenter USA 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

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China Medical Univ Hospital NCT03340792	Three 1 hour sessions per week for total of 40 sessions of ambulation training utilizing a ReWalk exoskeleton robot within a 3 month period	20-65yr Age SCI T4 and below	Chronic SCI SCI≥6m F/U 3m	Began 11/2017 China 10 Subjects	Phase N/A Single Group Open Label	Bone Mineral Density by dual X-ray absorptiometry SF-36 SCI-QOL Berg Balance Fat Mass/Lean Body Mass	Effects of Ambulation Training Utilizing an Exoskeleton Robot on Subjects With Spinal Cord Injury
Montecatone Rehabilitation Institute S.p.A. NCT03443700	EKSO-GT locomotor training plus 8 weeks standard locomotor training vs. 8 weeks of standard locomotor training alone	Age 18-65yr SCI T1-L1 AIS C, D Functional Gait (incl with braces)	Chronic SCI 1yr<SCI<5yrs	Not yet Begun Italy 40 Subjects	Phase N/A Parallel Group Single Blind	10MWT 6MWT WISCI II Ashworth LEMS EMG, SSEP, fMRI	RCT on Robotic Exoskeleton in Spinal Cord Injury: Clinical Outcomes and Cortical Plasticity
US Bionics NCT03175055	Open label safety and effectiveness study of the Phoenix exoskeleton device to enable standing and walking	Age≥18yrs T4 and below Stand with device Adequate bone health	Time post SCI NS F/U 10wks	Began 6/2017 Emeryville, CA Hong Kong 40 Subjects	Phase N/A Single Group Open Label	10MWT 6MWT TUG Variable Surface Walk Test	Evaluation of safety and effectiveness of the Phoenix exoskeleton device to enable standing and walking under variety of conditions
McGuire Research Institute NCT03410550	Powered exoskeleton (EKSO) 1 hour treatment sessions once or twice a week for 12 weeks	Age 18-70yrs Any SCI Level AIS NS Wt<220lbs	Chronic SCI SCI≥1yr F/U 12wks	Not yet Begun Richmond, VA 20 Subjects (10 complete SCI, 10 incomplete SCI)	Phase 2 Single Group Open Label	Blood Pressure Walking Time O2 Uptake Body Composition 6MWT, 10MWT, WISCI II EMG	Studying the effects of exoskeleton walking on cardiovascular, body composition, and walking parameters
University of Texas Houston NCT03057652	algorithmic-based evaluation and treatment approach for wearable robotic exoskeleton (WRE) gait training using ReWalk, Ekso, and REX systems; randomly assigned order of device use. Up to 15 training sessions per device.	Age≥18yr SCI level NS AIS NS Ashworth <3	Chronic SCI SCI>6m F/U 14-20wks	Began 3/2016 Houston, TX 75 Subjects	Phase N/A RCT Parallel Group Crossover Open Label	10 Meter Walk 6 Minute Walk Surface EMG Oxygen Consumption Gait Kinematics Bone Mineral Density	Development of an algorithmic-based evaluation and treatment approach for exoskeleton gait training
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

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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 NS 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

This table is abstracted from the clinical trial registration website www.clinicaltrials.gov using the search term "Spinal Cord Injury" and is updated periodically. The most recent update occurred March 5, 2018 at which time the www.clinicaltrials.gov search found a total of 886 SCI trials. Of these, there were 292 interventional trials that are enrolling or not-yet-enrolling. Review of these 292 studies for those that are targeting improvement in neurological or related functional outcomes yielded the current list. The table includes 71 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. Trials meeting these criteria are included if sufficient information is available on the clinicaltrials.gov webpages to adequately determine basic protocol design, the nature of the intervention, its delivery method, and relevant outcome measures.

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. The clinicaltrials.gov website is the largest repository of current and past clinical trials for all diseases and disorders—as of March 5, 2018 the registry contained information on 267,636 trials including research conducted in all 50 states in the USA and 203 countries. 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.

More detailed information on individual trials may be accessed by using the NCT number found in the first column of the table. All trials registered with www.clinicaltrials.gov are assigned a registration number that begins with NCT (e.g. NCT01321333). Entering the NCT number into the search field of www.clinicaltrials.gov or www.google.com will access the webpage describing the trial, the study centers, and contact information in more detail. When an electronic version of the tables is used (e.g. when downloaded as a pdf file from www.scope-sci.org), the webpages describing a specific trial can be directly accessed by using the hyperlink (left Click to follow the link) of the NCT number in the table. Listing of a clinical trial on the clinicaltrials.gov website does not reflect an endorsement SCOPE or by the National Institutes of Health. Information appearing on the clinicaltrials.gov website is provided by study sponsors/investigators and is not verified by SCOPE or clinicaltrials.gov for scientific validity or relevance. Before volunteering to participate in a clinical trial, patients are urged to discuss all options with their healthcare provider and other trusted advisors.

Terms/Abbreviations

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.

Ankle Clonus/foot drop test: a measure of spasticity

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

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).

BCI: Brain Computer Interface. Commonly using electroencephalographic ("Brain Wave") signals to interface with computerized control systems.

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

BMCA (Brain Motor Control Assessment): a surface electromyography-based measure of motor output from central nervous system during a variety of reflex and voluntary motor tasks performed under strictly controlled conditions.

BWSTT: Body Weight Supported Treadmill Training

COPM (Canadian Occupational Performance Measure): Interview assessment of an individual's perceived occupational performance in the areas of self-care, productivity, and leisure.

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

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

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

FDA: Food and Drug Administration

FES: Functional Electrical Stimulation. Using electrical stimulation of peripheral motor nerves to cause functional contraction of weakened/paralyzed muscles.

FMA-UL: Fugl-Meyer Assessment - Upper Limb, an assessment of upper extremity functional capacity

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

F/U: follow-up

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

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

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.

MEP: Motor Evoked Potentials, a physiological assessment of motor pathways performed by stimulating the motor cortex of the brain and recording muscle activation responses

N/A: not applicable

NS: not specified

OOPD: Office of Orphan Product Development

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.

Pendulum/Leg Drop Test: a measure of spasticity

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

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.**

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.

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.

SCATSR: Spinal Cord Assessment Tool for Spastic Reflexes, a measure of spasticity

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.

SCI-SET: 7-day recall self-report questionnaire that takes into account both the problematic and useful effects of spasticity on daily life in people with SCI.

SSEP: Somatosensory evoked potentials. A physiological assessment of nerve conduction in sensory pathways typically performed by electrically stimulating sensory nerves over the extremities and recording evoked responses with skin electrodes over the sensory cortex of the brain.

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

2 Minute Walk Test: the distance that can be walked in 2 minutes

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

Transcutaneous Spinal Cord Stimulation: stimulation of the spinal cord using electrodes applied to the skin; i.e. stimulation of the spinal cord through the skin

tDCS: Transcranial (through the skull) Direct Current Stimulation

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

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

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

WMFT: Wolf Motor Function Test