

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

Revised June 3, 2019 Listing 91 Trials

<u>Sponsor/NCT</u>	<u>Intervention</u>	<u>Inclusion/ Exclusion Criteria</u>	<u>Time Frames Post-SCI Follow-up</u>	<u>Enrollment</u>	<u>Study Phase Study Design</u>	<u>Outcome Measures</u>	<u>Comments</u>
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
University of Zurich Wings for Life NCT03534518	Body Weight Supported (BWS) overground training v. BWS treadmill training. 4 weeks of training	Age 18-70yr SCI above T12 AIS C, D Can walk 10m Speed≤1.1m/s 6MWT≤500m	Chronic SCI SCI>6m F/U 2m	Not yet begun Zurich 30 Subjects	Phase N/A RCT Parallel Group Open Label	6MWT	A study comparing overground vs treadmill for BWS 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 F/U 1yr	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
Brooks Rehabilitation University of Florida NCT03504826	Locomotor training with Cyberdyne Hybrid Assistive Limb (HAL) and locomotor training overground with or without the HAL device. 60 sessions (5 days/week for 12 weeks).	Age 18-80yrs Level NS AIS B, C, D Can walk 10ft	Chronic SCI SCI>1yr F/U 12wks	Began 11/2018 Jacksonville, FL 24 subjects	Phase N/A Single Group Open Label	10MWT, 6MWT EMG	Walking Rehabilitation After SCI: Locomotor Training Using Adaptive Robotics
Hospital Nacional de Paraplégicos de Toledo Institut Guttmann NCT03477123	Walking therapy with Exo-H2 exoskeleton vs. conventional walking therapy without robotic exoskeleton	Age 16-70yrs Level NS AIS C, D walker/crutch in walking rehab Height 1.6-1.9m	Subacute SCI Time post-SCI NS In Treatment at Study Center F/U 2m	Began 1/2016 <i>Enrolling by invitation</i> Multicenter Spain 20 Subjects	Phase N/A RCT Parallel Group Single Blind	LEMS Ashworth 10MWT, 6MWT, TUG WISCI II SCIM III	Evaluation of Robotic Exoskeletons Therapy for Gait Rehabilitation in Patients With Incomplete SCI
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 4mos	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 Castilla-La Mancha NCT03962218	Early (at time of enrollment) vs. Late (6 weeks after enrollment) Specific aquatic physiotherapy 40 minute sessions 3 times a week, for 6 weeks. The Late group will serve as an untreated control group, then receive the same aquatic physiotherapy regimen, beginning at 6 weeks after enrollment	Age 18-70yrs SCI T1-L5 AIS C, D Able to maintain assisted standing	Subacute, Chronic SCI<8mos F/U 12wks	Began 4/2019 Toledo, Spain 50 Subjects	Phase N/A RCT Crossover Single Blinded Assessment	Berg Balance 10MWT 6MWT WISCI II Health Related QoL Inflammatory Cytokines	Studying the effect of aquatic physiotherapy for improvement of balance and gait, inflammatory profile, and QoL

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

Revised June 3, 2019 Listing 91 Trials

<u>Sponsor/NCT</u>	<u>Intervention</u>	<u>Inclusion/Exclusion Criteria</u>	<u>Time Frames Post-SCI Follow-up</u>	<u>Enrollment</u>	<u>Study Phase Study Design</u>	<u>Outcome Measures</u>	<u>Comments</u>
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
Indiana University NCT03714997	Comparison of two different intensities of walking training (30 one-hour sessions on a treadmill, overground, and on stairs). High intensity training will target achievement of heart rates close to 80% of heart rate reserve; lower intensity to heart rates from 30% to 40% of heart rate reserve.	Age 18-75yr SCI C1-T10 AIS C, D Must tolerate 10m of standing without hypotension	Chronic SCI SCI≥1yr F/U 8wks	Not yet begun Indiana 80 Subjects	Phase 2 RCT Parallel Group Single Blind	10MWT	Study of the effects of walking training intensity on locomotor performance.
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
Khon Kaen University NCT03622710	Rehabilitation therapy training to walk overground (control) or over Different Surfaces (experimental) for 5 days/week over 4 weeks	Age≥18yrs SCI level NS AIS C, D Can walk 10m with or without assistive device	Subacute/Chronic SCI>3mos F/U 6mos	Began 7/2018 Thailand 72 Subjects	Phase N/A RCT Parallel Group Single Blind	10 meter walk test Timed Up and Go Sit to Stand 6 minute walk test Incidence of falls	Studying the effects of walking training using different surfaces on walking abilities and other outcomes
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

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

Revised June 3, 2019 Listing 91 Trials

Sponsor/NCT	Intervention	Inclusion/ Exclusion Criteria	Time Frames Post-SCI Follow-up	Enrollment	Study Phase Study Design	Outcome Measures	Comments
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	Phase N/A 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
Shepherd Center NIH NCT02340910	Two durations (eight 45sec @50Hz bouts vs. sixteen 45sec @ 50Hz bouts, 5 days/wk for 4 weeks) of Whole Body Vibration compared for improvement in spasticity and walking in persons with motor incomplete chronic SCI	16-72 Yr Age T12 or higher AIS C, D At least mild spasticity Tolerates standing Can sit without assist	Chronic SCI SCI ≥6m F/U 4wks	Began 1/2015 Atlanta 46 Subjects	Phase N/A RCT Parallel Group Open Label	Spasticity (Pendulum Test, SCI-SET, Electrophysiology) Walking Speed, Endurance Pinch Strength, 9-hole Peg Strength, Pain	Dose-Response Effects of Whole Body Vibration on Spasticity and Walking in SCI
Spinal Cord Injury Centre of Western Denmark NCT03690700	Active vs. Sham low-intensity blood-flow restricted exercise (BFRE): low-intensity strength training (20-30 % of max) while using circumferential cuffs during exercise adjusted to maintain arterial inflow to the muscles while preventing venous return.	Age 18-64yr Tetraplegia Elbow flex & Wrist extend strength 3-4/5 AIS A, B, C, D Speaks Danish	Subacute/Chronic SCI >1m F/U 12wks	Not yet begun Denmark 24 subjects	Phase N/A RCT Parallel Group Sham Control Single Blind	SCAR SF-36 GRASSP UE Strength H-Reflex, Ashworth, Tardieu VAS Pain Level TMS response	Active group upper arm cuff pressure to 30% above resting systolic BP; sham group to 50mmHg. 45m sessions 2X/wk for 8wks.
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	Age 18-85yr 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

Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org)

Current SCI Clinical Trials of Rehabilitation and Technological Interventions to Improve Functional Outcomes

Revised June 3, 2019 Listing 91 Trials

<u>Sponsor/NCT</u>	<u>Intervention</u>	<u>Inclusion/Exclusion Criteria</u>	<u>Time Frames Post-SCI Follow-up</u>	<u>Enrollment</u>	<u>Study Phase Study Design</u>	<u>Outcome Measures</u>	<u>Comments</u>
Third Affiliated hospital of Zhejiang Chinese Medical University NCT03909958	Electroacupuncture: five daily 30 minute sessions per week for 12 weeks. Subjects be randomly assigned to either receive electroacupuncture + routine rehab or routine rehab alone	Age 18-55yr Cervical SCI AIS C, D Grade 1-3 strength in BLE	Subacute SCI 14d \geq SCI \geq 30d F/U 6mos	Began 6/2019 Zhejiang, China 84 Subjects	Phase N/A RCT Parallel Group Open Label	fMRI ISNCSCI Ashworth Modified Barthel Index	Studying clinical effect of Electroacupuncture, as well as Brain Structural and Functional Changes
Instituto Nacional de Rehabilitacion NCT03531164	Kayak Ergometer training vs. neuroproprioceptive facilitation exercises focused on trunk control. 30 sessions (5 sessions per week for 6 weeks).	Age>16 SCI below C8 AIS NS	Chronic SCI 3m \leq SCI \leq 12m F/U 6wks	Began 4/2016 Mexico City 18 subjects	Phase N/A RCT Parallel Group Double Blind	Trunk Control SCIM III Heart Rate, Blood Pressure Satisfaction with Life questionnaire	Effect of Kayak Ergometer Training in trunk control, independence and cardiovascular health in persons with SCI
Hugo Moser Research Inst. NINDS NCT03854214	FES Cycling with RT300 ergometer vs. Passive (Sham/without FES) Cycling. One hour sessions 3 times per week for 4 weeks	Age 18-65yr Thoracic SCI AIS A, B, C, D	Chronic SCI SCI>6m F/U 4wks	Not yet begun Baltimore 48 Subjects	Phase N/A RCT Parallel Group Double Blind	ISNCSCI fMRI	Does FES Cycling result in changes in brain connectivity, correlating with neurorecovery
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 \geq 18yrs SCI C4-C7 AIS B, C, D SCIM-SC \leq 10	Chronic SCI 4m<SCI<18m 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 SCI-QOL	comparing electrical neuromodulation delivered by MyndMove® therapy to intensive upper-limb conventional therapy
Milos Popovic Toronto Rehabilitation Institute NCT03658798	Forty 1 hour treatment sessions of UE surface FES utilizing a prototype FES-shirt garment (GarmentGrasp) with embedded electrodes and wires custom-positioned to enable stimulation of muscles around the hand, elbow, and shoulder	18-70yrs Age SCI C4-C7 AIS NS	Chronic SCI SCI>6m F/U 14wks	Began 10/2017 Toronto 24 Subjects (12 with SCI, 12 with stroke)	Phase N/A Single Group Open Label	TRI-HFT FIM SCIM Grip Strength Task performance with/without FES	Grasping rehabilitation with functional electrical stimulation garment (GarmentGrasp)
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 \geq 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

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

Revised June 3, 2019 Listing 91 Trials

<u>Sponsor/NCT</u>	<u>Intervention</u>	<u>Inclusion/ Exclusion Criteria</u>	<u>Time Frames Post-SCI Follow-up</u>	<u>Enrollment</u>	<u>Study Phase Study Design</u>	<u>Outcome Measures</u>	<u>Comments</u>
SCI Centre of Western Denmark Aarhus University Hospital Regionshospitalet Viborg University of Southern Denmark NCT03441256	laparoscopic implantation of neuroprosthesis (LION) electrical stimulation of the lumbosacral plexus vs. conventional surface electrode neuromuscular electrical stimulation	Age 18-45yrs SCI T6-L1 AIS A, B	Chronic SCI SCI≥12m F/U 12m	Began 1/2018 Denmark <i>Enrolling by invitation</i> 20 Subjects	Phase N/A RCT Parallel Group Open Label	WISCI III Electrophysiology Lower Urinary Tract Function Bowel Function QoL (SF-36) Brief Pain Inventory	Study of Motor, Sensory, and Autonomic Function After LION stimulation of the lumbosacral plexus
Louis Stokes VAMC NCT01570816	Device: IRS-8 (8 channel implanted receiver stimulator) to study the effect of functional electrical stimulation of the hip, knee and ankle muscles to improve walking in people with partial paralysis	18-75yr age Impaired walking due to chronic partial paralysis Walk ≥10 with min assist	Chronic iSCI SCI≥6m F/U up to 36m	Began 4/2012 Cleveland, OH 6 Subjects	Phase 1 Single Group Open Label	Analyses of speed, distance and quality of walking with and without stimulation Feasibility of initiating a step with a trigger from an accelerometer incorporated in the external control unit.	Surgical implantation to stimulate paralyzed muscles of the lower extremities
Clinique Beau Soleil University Hospital, Montpellier NCT03721861	Intra-operative neural cuff stimulation. A feasibility study for placement of 2 electrodes around the radial or medial nerves intraoperatively during tendon transfer surgery to restore elbow extension	Age 18-65yr NLI≥C7 AIS A, B Undergoing surgery to restore elbow extension	Chronic SCI SCI>6m F/U 1wk	Began 2/2016 Montpellier, France 9 subjects	Phase N/A Single Group Open Label	Selectivity of cuff electrode nerve stimulation responses for activation of UE muscle contractions	Neural Functional Electrical Stimulation for the recovery of grasping movements for patients with tetraplegia
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 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

Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org)

Current SCI Clinical Trials of Rehabilitation and Technological Interventions to Improve Functional Outcomes

Revised June 3, 2019 Listing 91 Trials

<u>Sponsor/NCT</u>	<u>Intervention</u>	<u>Inclusion/Exclusion Criteria</u>	<u>Time Frames Post-SCI Follow-up</u>	<u>Enrollment</u>	<u>Study Phase Study Design</u>	<u>Outcome Measures</u>	<u>Comments</u>
Case Western Reserve University NIH Dept Veterans Affairs 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
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
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
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≥22yr 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
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

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

Revised June 3, 2019 Listing 91 Trials

<u>Sponsor/NCT</u>	<u>Intervention</u>	<u>Inclusion/ Exclusion Criteria</u>	<u>Time Frames Post-SCI Follow-up</u>	<u>Enrollment</u>	<u>Study Phase Study Design</u>	<u>Outcome Measures</u>	<u>Comments</u>
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
University of Louisville NCT03949660	Must be already be enrolled in epidural spinal stimulation and training study. Various epidural stimulation protocols will be performed with assessments of bowel function and QoL.	18-75yr Age SCI Level NS AIS A, B Cardiovasc & bowel dysfunction	Chronic SCI SCI ≥2yrs F/U 20mos	Not yet begun Louisville, KY 36 Subject	Phase N/A RCT Parallel Group Crossover Open Label	Wireless Bowel Motility Capsule Blood Pressure, Heart Rate Anorectal Pressure Bowel Diary SCI-QoL	Studying Epidural Stimulation & Training for improved Bowel Function and QoL
University of Calgary NCT03924388	Short term (single 1 hour session) and long term (5 one hour sessions per week for 4 weeks) transcutaneous spinal cord stimulation. Will also study autonomic function in a small group of subjects previously implanted with epidural stimulator.	18-65yr Age SCI Level NS AIS NS Has Cardiovasc dysfunction	Chronic SCI SCI ≥1yr F/U 4wks	Not yet begun Calgary Vancouver 46 Subjects	Phase N/A (Pseudo) RCT 2x2 Factorial Open Label	Blood Pressure Blood Flow Heart Rate Sympathetic Skin Response Urodynamics EMG ISNCSCI	Studying the effects of spinal cord stimulation on autonomic function
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 15mos	Began 8/2017 Minneapolis 100 Subjects	Phase N/A Single Group Single Blinded Outcome (BMCA)	Brain Motor Control Assessment Volitional Movement Blood Pressure Cerebral Blood Flow (tilt table) Arterial Stiffness Urinary Bladder Control	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

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

Revised June 3, 2019 Listing 91 Trials

<u>Sponsor/NCT</u>	<u>Intervention</u>	<u>Inclusion/Exclusion Criteria</u>	<u>Time Frames Post-SCI Follow-up</u>	<u>Enrollment</u>	<u>Study Phase Study Design</u>	<u>Outcome Measures</u>	<u>Comments</u>
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
University College, London Neurokinex Inspire Foundation Royal National Orthopaedic Hospital NHS Trust NCT03536338	Electrical stimulation applied to the skin surface at the lower back with sit-to-stand training vs. sit-to-stand training alone. 3 sessions per week for 8 weeks.	Age>18yrs C5-T12 SCI AIS A, B, C, D Unable to stand from chair unaided	Chronic SCI SCI>1yr F/U 8wks	Not yet begun London, UK 10 subjects	Phase N/A Non-random Parallel Group Open Label	LE Motor Control (EMG) Sit-to-stand Performance QoL Urodynamics	Spinal Stimulation Sit-to-Stand Training After Spinal Cord Injury (Stim2Stand)
University of Florida NIH NICHD NCT03702842	transcutaneous direct current stimulation (tsDCS) of the spinal cord utilizing Soterix Medical tsDCS stimulator over the low back during locomotor training. Part 1: 2 sessions with different stimulation levels; Part 2: 16 sessions of locomotor training with one of the two tsDCS dosages	Age 18-65yr NLI T12 or above AIS C, D Can walk 10ft with/without aids/assist	Chronic SCI SCI>1yr F/U 4wks	Began 4/2019 Jacksonville, Florida 20 Subjects	Phase N/A RCT Parallel Group Single Blind (Participant)	10MWT EMG 6MWT	Study to explore effects of tsDCS applied during walking in adults with chronic iSCI
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 Bladder Pressure Voiding Efficiency Rectal pressure	Functional Mapping With Lumbosacral Epidural Stimulation for Restoration of Bladder Function After SCI
Shirley Ryan Ability Lab/UCLA NCT03922802	30 sessions of up to 50 min of conventional locomotion training with or without simultaneous transcutaneous spinal cord stimulation using skin electrodes	Age≥18yrs SCI below C2 AIS A, B, C, D	Subacute to Chronic SCI≥4wks F/U 12mos	Not yet begun Chicago, IL 36 subjects	Phase N/A RCT Parallel Group Open Label	Gait Kinematics 10MWT 6MWT with O ₂ Consumption	Study of effectiveness of transcutaneous (non-invasive) spinal cord stimulation on gait and balance function
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 Enrolled in inpatient rehab or outpatient Day Program at Shepherd Center	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 Tolerance of stimulation	Combined Influence of Transcutaneous Spinal Cord Stimulation and Locomotor Training on Spasticity and Walking Outcomes

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

Revised June 3, 2019 Listing 91 Trials

<u>Sponsor/NCT</u>	<u>Intervention</u>	<u>Inclusion/ Exclusion Criteria</u>	<u>Time Frames Post-SCI Follow-up</u>	<u>Enrollment</u>	<u>Study Phase Study Design</u>	<u>Outcome Measures</u>	<u>Comments</u>
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 \geq 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
City University of New York Bronx Veterans Medical Research Foundation, Inc NCT03669302	20 sessions of low(0.3Hz)- vs. high(30Hz)-frequency transspinal (surface electrical) stimulation in persons receiving robotic gait training to improve LE motor function after motor incomplete SCI	18-65yr Age SCI above T12 (vertebral) AIS C, D	Chronic SCI SCI \geq 6m F/U 3yr	Began 8/2018 New York 45 Subjects	Phase N/A RCT Parallel Group Open Label	Neurophysiological Testing TMS responses H-Reflex ISNCSCI Tardieu Scale (spasticity) 2MWT, 10MWT	Activity-Dependent Transspinal Stimulation for Recovery of Walking Ability After SCI
U of Washington NCT03509558	Transcutaneous cervical and lumbosacral electrical stimulation with intensive walking and standing physical therapy vs. intensive walking and standing physical therapy alone. 2hr/day, 2-5d/week.	21-70yr Age SCI T12 or higher Incomplete SCI	Chronic SCI SC \geq 1yr F/U 11m	Began 2/2018 Seattle, WA 10 subjects	Phase N/A RCT Crossover Open Label	Neuromuscular Recovery Scale ISNCSCI SSEP, MEP Berg Balance, 6MWT, 10MWT Kinematics SCI-QOL, SCI-FI	Transcutaneous Spinal Stimulation and Exercise for Locomotion
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 \geq 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
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 \geq 12m F/U 8-12m	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, Pain Assessment Kinematics, EMG Electrophysiology	Single group study of the combination of closed-loop EES with robotic assisted rehabilitation in chronic iSCI

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

Revised June 3, 2019 Listing 91 Trials

<u>Sponsor/NCT</u>	<u>Intervention</u>	<u>Inclusion/ Exclusion Criteria</u>	<u>Time Frames Post-SCI Follow-up</u>	<u>Enrollment</u>	<u>Study Phase Study Design</u>	<u>Outcome Measures</u>	<u>Comments</u>
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
Bronx VA Medical Center NCT03806023	Utilization of EMG detection of thumb muscle contraction to trigger peripheral (median nerve) stimulation and/or transcranial magnetic stimulation, either at rest or attempting pinch task. Five different 20-minute interventions (combinations of above).	Age 18-75yr SCI C2-C8 ≥3/5 strength of finger ext, flex, abduct. APB MEP, FWave responses	Chronic SCI SCI>12m F/U 1 day	Began 2/2018 Bronx, NY 20 Subjects	Phase N/A Single Group Open Label	Motor Evoked Potential Hand Dexterity Grip Strength	Possible foundation for future studies combining EMG-triggered stimulation with long-term physical exercise training
Burke Medical Research Institute NCT03592173	Spinal Associative Stimulation (SAS) with repetitive and synchronized dual peripheral nerve and brain stimulation; i.e. Paired Associative Stimulation (PAS) to enhance MEP amplitude in target muscles	18-80yr Age NLI NS AIS C, D LEMS≥3 Some spared ankle flex/extend	Chronic SCI SCI>6m F/U 3wks	Began 7/2013 White Plains, New York 30 Subjects	Phase 2 RCT Parallel Group Crossover Open Label	H-Reflex LEMS WISCI II 10MWT SCIM III Muscle force, Kinematics	Testing various stimulus pairing times. Each session of three sessions includes 90 paired stimuli over 15 min
Helsinki Central University Hospital Validia Rehabilitation Centre NCT03459885	Paired Associative Stimulation (PAS) using transcranial magnetic stim paired with Lower Extremity (LE) peripheral nerve electrical stimulation administered several times per week for 8 weeks	Age 18-70yr Cervical SCI AIS B, C, D	SCI duration NS F/U 3m	Began 2/2018 Finland <i>Enrolling by invitation</i> 5 Subjects	Phase N/A Single Group Open Label	Manual Muscle Testing	Long-term PAS for rehabilitation of LE in Persons With Incomplete Tetraplegia
Helsinki Central University Hospital Validia Rehabilitation Centre NCT03045744	Paired Associative Stimulation (PAS) using transcranial magnetic stim paired with Lower Extremity (LE) peripheral nerve electrical stimulation administered several times per week for as long as continuous improvement is observed	Age 18-70yr SCI level NS AIS B, C, D	SCI duration NS F/U until 1m after last stimulation session	Began 2/2017 Finland <i>Enrolling by invitation</i> 5 Subjects	Phase N/A Single Group Open Label	Manual Muscle Testing	Long-term PAS for rehabilitation of LE function; extending participation for as long as improvement is observed
VA Office of R&D University of Miami NCT03447509	Transcranial non-invasive Magnetic Stimulation targeting late indirect descending volleys (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	Began 8/2018 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

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

Revised June 3, 2019 Listing 91 Trials

<u>Sponsor/NCT</u>	<u>Intervention</u>	<u>Inclusion/Exclusion Criteria</u>	<u>Time Frames Post-SCI Follow-up</u>	<u>Enrollment</u>	<u>Study Phase Study Design</u>	<u>Outcome Measures</u>	<u>Comments</u>
Spinal Cord Injury Centre of Western Denmark University of Southern Denmark NCT03690726	Active vs. sham Repetitive transcranial magnetic stimulation (rTMS) combined with strength training/standard of care rehabilitation	18-50yr Age NLI NS AIS B, C, D	Subacute/Chronic SCI<6m F/U 8wks	Not yet begun Denmark 30 Subjects	Phase N/A RCT Parallel Group Sham Control Triple Blind	6MWT, 10MWT LEMS TUG WISCI ISNCSCI Pain VAS	Study of rTMS effects on recovery of motor function when combined with strength training/rehab
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 20 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	Began 5/2018 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
Cleveland Clinic US Department of Defense NCT03892746	Non-invasive brain stimulation tDCS (Transcranial Direct Current Stimulation) vs. sham tDCS to the area in the brain controlling the weaker muscle of the weakest upper limb while receiving task-oriented training for 15 Session (5d/wk X 3wks)	18-75yr Age Cervical SCI Level NS AIS NS Triceps strength of weaker UE is 1 grade< stronger UE	Chronic SCI SCI≥1yr F/U 3mos	Not yet begun Cleveland, OH 44 Subjects	Phase 1/2 RCT Parallel Group Double Blind	ISNCSCI UEMS GRASSP Ashworth COPM SCIM TMS Thresholds H-reflex	Testing a novel method of non-invasive brain stimulation in conjunction with upper limb training

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

Revised June 3, 2019 Listing 91 Trials

<u>Sponsor/NCT</u>	<u>Intervention</u>	<u>Inclusion/Exclusion Criteria</u>	<u>Time Frames Post-SCI Follow-up</u>	<u>Enrollment</u>	<u>Study Phase Study Design</u>	<u>Outcome Measures</u>	<u>Comments</u>
Burke Medical Res. Institute New York State SCI Res. Board NCT03555838	6-week hand robotic training preceded by 20 min anodal 2mA transcranial electrical direct-current stimulation (tDCS) or sham procedure (3 sessions/week, 18 sessions total)	18-99yr Age Cervical SCI AIS B, C, D Hand weakness Pick up ≥ 1 block in Box & Block	Chronic SCI SCI>6m F/U 10wks	Began 5/2017 New York 40 Subjects	Phase 3 RCT Parallel Group Double Blind	Box and Blocks Test UEMS, SCIM III Ashworth 9-hole Peg Test QIF Chronic Pain Questionnaire	Improving Hand Function in Chronic SCI With Combined Robotic Training and tDCS
The University of Kentucky Wings for Life NCT03954496	20 minute non-invasive Active vs. Sham brain stimulation (tDCS) sessions followed by 2 hours of intensive UE Motor Training. Number of sessions NS.	18-65yr Age C4-C7 AIS B, C, D	Chronic SCI SCI ≥ 1 yr F/U 4mos	Not yet begun Kentucky 36 Subjects	Phase N/A RCT Parallel Group Double Blind	SCIM MRC MMT COPM GRASSP Van Lieshout Test TMS Cortical Mapping	Improving Hand Recovery With tDCS Neuromodulation in Tetraplegia
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 ≥ 6 m 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
Shepherd Center NIH NCT02340910	Two durations (eight 45sec @50Hz bouts vs. sixteen 45sec @ 50Hz bouts, 5 days/wk for 4 weeks) of Whole Body Vibration compared for improvement in spasticity and walking in persons with motor incomplete chronic SCI	16-72 Yr Age T12 or higher AIS C, D	Chronic SCI SCI ≥ 6 m F/U 4wks	Began 1/2015 Atlanta 57 Subjects	Phase N/A Parallel Group Open Label	Spasticity (Pendulum Test, SCI-SET, Electrophysiology) Walking Speed, Endurance Pinch Strength, 9-hole Peg Strength, Pain	Dose-Response Effects of Whole Body Vibration on Spasticity and Walking in SCI
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 ≤ 3 hr 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.

Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org)

Current SCI Clinical Trials of Rehabilitation and Technological Interventions to Improve Functional Outcomes

Revised June 3, 2019 Listing 91 Trials

<u>Sponsor/NCT</u>	<u>Intervention</u>	<u>Inclusion/Exclusion Criteria</u>	<u>Time Frames Post-SCI Follow-up</u>	<u>Enrollment</u>	<u>Study Phase Study Design</u>	<u>Outcome Measures</u>	<u>Comments</u>
VA Office of Research and Development Case Western Reserve University NCT03482310	Use of Neuroport array to record cortical activity to train the development of brain activity correlated with appropriate grasp patterns, utilizing virtual reality and FES controlled hand movement. Eligible subjects must have been successful participants in BrainGate2 trial.	Age NS SCI with UE impairment Neuroport implant Braingate2 participant	Chronic SCI Time post SCI NS F/U 1yr	Began 6/2018 Cleveland, OH 6 Subjects	Phase N/A Single Group Open Label	Ability to form appropriate grasp patterns	Restoring High Dimensional Hand Function to Persons With Chronic High Tetraplegia
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
Michael Boninger University of Pittsburgh 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
Synchron Medical, Inc NCT03834857	Intravascular placement via the jugular vein of stent electrode (Stentrode™) into a vessel in the motor cortex in the brain. The electrode is positioned so that brain motor activity signals can be captured and sent to a wireless antenna unit implanted in the chest, which sends them to an external receiver.	18-75yr Age SCI level NS AIS NS Normal brain venous sinus anatomy on imaging studies	Chronic SCI SCI ≥12mos F/U 36mos	Began 6/2019 Melbourne, Australia 5 Subjects	Phase N/A Single Group Open Label	Treatment-related Adverse Events Fidelity and Stability of brain wave signals recorded from Stentrode™	First in human early feasibility study of intravascular stent electrode Stentrode™ in brain blood vessel.

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

Revised June 3, 2019 Listing 91 Trials

<u>Sponsor/NCT</u>	<u>Intervention</u>	<u>Inclusion/ Exclusion Criteria</u>	<u>Time Frames Post-SCI Follow-up</u>	<u>Enrollment</u>	<u>Study Phase Study Design</u>	<u>Outcome Measures</u>	<u>Comments</u>
National Neuroscience Institute NCT03811301	Surgical placement of 4.4mm by 4.2mm electrode array onto the surface of the motor cortex of the brain to enable wireless recording and transmission of brain wave signals for control of external assistive devices. Neural signals are recorded at least once every week for 12 months or longer.	Age 21-70yr Tetraplegia AIS NS Able to participate in BMI training	Time after SCI NS F/U 1yr	Began 11/2017 Singapore 3 Subjects	Phase 2 Single Group Open Label	Serious Adverse Events Signal Quality from Electrodes Decoding Accuracy Number of Successful Trials during session	Study to enable the development of wireless implantable BMI system for control of assistive devices
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	Age 22-65yr 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
Northwell Health NCT03680872	Bidirectional Neural Bypass System: Implantation of microelectrode arrays into the primary motor cortex to record neural activity associated with desired movements and into the primary somatosensory cortex to deliver stimulation in order to provide sensory perception. Participation in 3 study session/wk X 12mos	22-65yr Age Motor Level C5 AIS A	Chronic SCI SCI≥1yr F/U 12m	Began 9/2018 Manhasset, New York 3 Subjects	Phase N/A Single Group Open Label	GRASSP-restoration of hand movement Restoration of tactile sensation of the hand	Feasibility trial of brain implantation of Bidirectional Neural Bypass System for restoration of hand movement and sensation
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 Glasgow, UK 20 Subjects	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
University of California, San Francisco NCT03698149	Brain implantation of cortical electrodes to enable electrocorticography (ECoG) recording of brain activity. Study subjects will undergo training and assessment of their ability to control a wearable hand robotic exoskeleton and/or produce speech	Age>21yrs Limited UE use due to SCI or other neuro disability. Lives close to UCSF	Chronic SCI SCI≥1yr F/U 6yr	Began 8/2018 San Francisco 8 Subjects	Phase 1 Single Group Open Label	Adverse Events associated with ECoG-based interface	Feasibility of using electrocorticography (ECoG) signals to control complex devices for motor and speech control

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

Revised June 3, 2019 Listing 91 Trials

<u>Sponsor/NCT</u>	<u>Intervention</u>	<u>Inclusion/ Exclusion Criteria</u>	<u>Time Frames Post-SCI Follow-up</u>	<u>Enrollment</u>	<u>Study Phase Study Design</u>	<u>Outcome Measures</u>	<u>Comments</u>
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
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
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 C1-T10 AIS C, D Can use Front-Wheeled Walker Amb<0.44m/sec	Chronic SCI Community-dwelling F/U 24 wks	Began 9/2016 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
Ekso Bionics NCT02566850	Home-setting high dosage use of an Ekso powered exoskeleton device (with a trained spotter at all times)	18-65yr Age <i>Experienced Ekso user</i> requiring≤min assist 60"-76" height	Chronic SCI Community-dwelling F/U 12-36mos	Began 1/2014 <i>Enrolling by invitation</i> Location NS 12 subjects	Phase NA Single Group Open Label	Adverse Events QoL Bowel & Bladder Function ISNCSCI, Ashworth SCIM II, Exertion (Borg) Bone Density (DEXA)	Safety and health effects of using the Ekso device (and trained spotter) in a home setting over 12-36 mos

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

Revised June 3, 2019 Listing 91 Trials

<u>Sponsor/NCT</u>	<u>Intervention</u>	<u>Inclusion/Exclusion Criteria</u>	<u>Time Frames Post-SCI Follow-up</u>	<u>Enrollment</u>	<u>Study Phase Study Design</u>	<u>Outcome Measures</u>	<u>Comments</u>
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 Taiwan 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
Taipei Veterans General Hospital, Taiwan The Industrial Technology Research Institute NCT03548649	At least 20 training sessions (1 hour per session, 2-5 sessions per week) with the FREE Walk exoskeleton robot	18-70yr Age SCI C5-L5 AIS A, B, C, D Can use forearm crutches; cannot walk without assistive device	Chronic SCI SCI≥3m F/U 4-10wks (at the end of 20 sessions)	Began 8/2017 <i>Enrolling by invitation</i> Taiwan 60 Subjects	Phase N/A Single Group Open Label	10MWT TUG 6MWT	Efficacy and safety of a new powered exoskeleton robot for improving walking ability in SCI patients
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
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	Began 7/2018 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
Shirley Ryan Ability Lab Otto Bock Healthcare Products NCT03930056	C-Brace II use vs. traditional KAFO use. Following evaluation and brace fitting, participants will receive 10-20 one hour training sessions with assigned brace, then transition to home use for 3 month period.	18-80yr Age SCI Level NS AIS NS Requires LE orthotic bracing including knee for instability	Chronic SCI 3mos≥SCI≥24mos F/U 12mos	Began 4/2019 Chicago, IL 30 Subjects	Phase N/A RCT Parallel Group Open Label	6MWT 10MWT MMT LE ROM Ashworth WISCI Gaitrite Data Capture	Study of Micro-Processor Controlled Knee-Ankle-Foot Orthosis (C-Brace) vs. standard KAFO in persons with SCI to determine functional outcome differences.

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

Revised June 3, 2019 Listing 91 Trials

<u>Sponsor/NCT</u>	<u>Intervention</u>	<u>Inclusion/ Exclusion Criteria</u>	<u>Time Frames Post-SCI Follow-up</u>	<u>Enrollment</u>	<u>Study Phase Study Design</u>	<u>Outcome Measures</u>	<u>Comments</u>
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 1/2 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 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 June 3, 2019 at which time the www.clinicaltrials.gov search found a total of 1045 SCI trials. Of these, there were 301 interventional trials that are enrolling or not-yet-enrolling. Review of these 301 studies for those that are targeting improvement in neurological or related functional outcomes yielded the current list. The table includes 91 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 June 3, 2019 the registry contained information on 307,343 trials including research conducted in all 50 states in the USA and 210 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 webpages 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

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

Revised June 3, 2019 Listing 91 Trials

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 or BMI: Brain Computer Interface or Brain Machine Interface. Use of 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.

Borg Perceived Rate of Exertion: a measurement scale of a subject’s perceived effort

Box and Blocks Test: a timed functional test to determine gross manual dexterity.

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.

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

Revised June 3, 2019 Listing 91 Trials

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

GAITRite® : is a portable pressure sensitive walkway for measurement of temporal and spatial gait parameters.

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.

LE: Lower Extremity

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

Revised June 3, 2019 Listing 91 Trials

Medical Research Council manual muscle testing (MRC MMT): scale of 0-5 commonly used for grading the strength of a given muscle.

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

NRS: Neuromuscular Recovery Scale. Performance assessment of functional motor recovery that includes seated sit up and reverse sit up, sitting ability, trunk extension in sitting, standing ability, walking ability, and sit to stand

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

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.

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

Revised June 3, 2019 Listing 91 Trials

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.

SCAR: Spinal Cord Ability Ruler is a test of performance capacity for persons with SCI combining scores of SCIM and the upper limb motor assessments of ISNCSCI

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

SCI-FI: Spinal Cord Injury Functional Index. A measure of physical functioning in persons with SCI

SCI-FAP: Spinal Cord Injury Functional Ambulation Profile. Time it takes to do 7 specific walking tasks: 5 meters on carpet, 5 meters on smooth ground while carrying a bag with weights, timed-up-and-go, up and down one step, up and down 4 steps, walking while opening a door, walking over and around obstacles

SCI-QOL: Spinal Cord Injury Quality of Life measure

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.

Sham: is a “faked” clinical trial procedure that omits the elements thought to be therapeutically necessary, analogous to a placebo in a drug trial. Sham procedures are often used in control groups of parallel group trials to enable more accurate assessment of the “active” treatment by enabling blinding of subject and outcome assessor.

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

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

Revised June 3, 2019 Listing 91 Trials

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

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

Tardieu Scale: a measure of spasticity utilizing slow vs. fast passive stretch of examined muscle(s) in order to distinguish contracture from spasticity

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

TMS, tMS: Transcranial Magnetic Stimulation uses surface (over the scalp) magnetic field stimulation of the motor cortex of the brain to produce motor responses in limb musculature

tDCS: Transcranial (through the skull) Direct Current Stimulation uses surface (over the scalp) electrical field stimulation of the motor cortex of the brain to produce motor responses in limb musculature

TRI-HFT: Toronto Rehabilitation Institute Hand Function Test, a clinical measure of hand function in which a series of movement and object manipulations are video-taped, timed, and rated for their quality of execution and success.

UE: Upper Extremity

Van Lieshout Test (VLT): a 19-item test used to evaluate upper extremity motor performance in 5 areas of interest: 1) arm ability to transfer the body, 2) arm positioning and stabilizing, 3) hand opening and closing, 4) grasping and releasing, and 5) manipulating.

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