

Rehabilitation Interventions and Therapies



Figure 1:Locomotor Training at a Reeve NRN facility.

The following interventions will be discussed below:

- Locomotor or Treadmill Training
- Functional Electrical Stimulation (FES)
- Neuromuscular Electrical Stimulation (NMES)
- Epidural Stimulation (ES)
- Transcutaneous Stimulation (TS)
- Exoskeletons

Many of these activities have numerous names ranging from the clinical phrase "neurorehabilitation movement therapy" to more casual names such as "treadmill therapy"; some are invasive, and some are not. Some of these activities take place in clinical centers while others may take place in the community. Many involve movement or exercise. What they have in common is that they are activities or interventions employed for rehabilitative purposes. All of them aim to return functions, improve health, and generally improve the quality of life for people living with paralysis. The term "therapy" is usually only used if the activity is supervised by health care professionals who may include physical therapists and occupational therapists. The term "intervention" is the more common term when the activity is not being overseen by health care professionals.

(Note: Before considering participation in advanced rehabilitation therapies, such as FES or treadmill training, it is important to be evaluated by one's own physician to ensure that the therapies are appropriate and safe.)

Christopher Reeve's experience with some of these interventions

Christopher Reeve demonstrated to the world he recovered some movement and sensation. While he was not able to walk, did not regain bowel, bladder, or sexual function, his limited recovery is still significant. The scientific literature on spinal cord injury predicts that most recovery will occur in the first six months after injury and that it is generally complete within two years. Reeve's recovery, coming five to seven years after his injury, defied these medical expectations and had a dramatic effect on his daily life.

Why did he get better so long after his injury? Reeve believed his improved function was the result of vigorous physical activity. He began exercising the year he was injured. Five years later, when he first noticed that he could voluntarily move an index finger, Reeve began an intense exercise program under the supervision of Dr. John McDonald at Washington University in St. Louis.

Reeve included several activities in his program. He used daily electrical stimulation to build mass in his arms, quadriceps, hamstrings and other muscle groups. He rode a Functional Electrical Stimulation (FES) bicycle, did spontaneous breathing training and

also participated in aqua therapy. In 1998 and 1999, Reeve underwent treadmill training to encourage functional stepping.

Reeve and Dr. McDonald suggested that these activities may have awakened dormant nerve pathways. The fact is, however, that it is not possible in a single experiment to know just what did occur in Reeve's nervous system. To be sure, his recovery may have been related to exercise. Dr. McDonald and other researchers and clinicians caution not to over-interpret Reeve's results. Clearly, not all people with paralysis would benefit from a similar program.

Said McDonald in the *Journal of Neurosurgery – Spine*, "Although we cannot conclude that the activity-based recovery program produced the functional benefits, we believe it was responsible for the physical benefits."

It is true for any of us: exercise is related to better health. Because there are few, if any, negative side effects of exercise, even people who don't experience recovery in the way that Reeve had are likely to improve their well-being. For Reeve, a high quad on a ventilator, improved health was the single most important benefit of his exercise and therapy program.

Reeve's participation in exercise was motivated by the well-known benefits on cardiovascular function, muscle tone, bone density, etc. Indeed, after his participation, he experienced fewer medical complications such as bladder and lung infections. Before 1999, Reeve frequently required hospitalization – he had a total of nine life-threatening complications and required almost 600 days of antibiotic treatment. Since 1999 until his untimely death in 2004, he had not been hospitalized, had only one serious medical complication, and needed only 60 days of antibiotic treatment. These improvements in his health boosted Reeve's emotional well-being and enabled him to commit to a variety of work projects knowing he could give them his uninterrupted attention.

If Reeve's recovery of function was due to the exercise, it was a wonderful side effect. Now, scientists are undertaking detailed studies and working with large numbers of people in centers across the country to give them the chance for similar benefits. Although it is not clear what caused his recovery, his improvements in function provide a source of hope and inspiration for others.

Reeve was a strong advocate for making FES technology more widely available. "I have the staff and the equipment," he said. "But what I really hope comes out of my experience is a paradigm shift in the way insurance companies do business. If insurance companies would pay for proactive therapy and equipment they would save money keeping people like me out of the hospital. People with lower level injuries would get up and get out of their chairs. It's a win-win proposition."

Functional Electrical Stimulation (FES)



Figure 2:Photo Courtesy of Chanda Plan.

This technology allows persons with little or no voluntary leg movement to pedal a stationary leg-cycle called an ergometer. Computer generated, low-level electrical pulses are transmitted through surface electrodes to the leg muscles; this causes coordinated contractions and the pedaling motion.

FES bikes are not new; they have been on the market for over 30 years. There are two companies now manufacturing FES bikes in the U.S., Therapeutic Alliances, Inc., makers of the ERGYS 3, and Restorative Therapies, which has a bike that can be used by children as young as four years old. These bikes are not cheap – some are in the range of \$15,000. Some insurance companies have reimbursed for units. There are bikes available in some community settings, at health clubs and rehab clinics. Various rehabilitation hospitals may also offer FES therapies.

The first step is to choose a bike that is mechanically sound. All the electronics are upgradeable from the manufacturers. Each bike has a program cartridge set up for the specific needs of each rider, including run times, resistance, etc. A prescription is needed to get the cartridge. For safety reasons, it's not recommended that FES bike riders use another's cartridge.

Abundant medical literature documents the effectiveness of FES to increase muscle mass and improve cardiopulmonary function. There are studies that also link FES to a reduced frequency of pressure sores, improved bowel and bladder function and decreased incidence of urinary tract infections.

To find a rehab center near you that offers FES, please go to CARF's site (<u>www.carf.org</u>) and find a rehab center in your area that specializes in your diagnosis (SCI, etc.) and then contact them to see if they offer i.

FES Resources

The following are a list of websites of manufacturers and vendors who provide FES bikes and other FES products. Please note a listing here is not an endorsement; the sites below are offered for informational purposes only.

FES Equipment

Bioness

www.bioness.com www.bionessmobility.com Phone: 855-902-5252

Bioness is a leading provider of innovative technologies helping people regain mobility and independence. Bioness' products include FES systems that provide therapeutic benefits for individuals affected by central nervous system disorders and orthopedic injuries.

Bioness H200 for Hand Paralysis

https://www.bioness.com/Products/H200_for_Hand_Paralysis/What_is_It.php

Bioness L300 for Foot Drop

https://www.bioness.com/Products/L300_for_Foot_Drop/What_is_It.php

Myolyn

https://myolyn.com 6931 NW 22nd St., Suite A Gainesville, FL 32653 Phone: 352-306-8479 Email: myolyn@myolyn.com

There's a new FES bike on the scene called the MyoCycle. They offer information on financial options for purchasing the MyoCycle. MyoCycle is designed for use at home.

Restorative Therapies Inc.

http://www.restorative-therapies.com

Phone: 800-609-9166

Dr. John McDonald founded an activity-based therapy using FES equipment that is called Restorative Therapy. Restorative Therapies Inc., based in Baltimore, MD, is a leading developer of Functional Electrical Stimulation (FES) powered systems, designed to help people with neurological disorders or people in critical care achieve their full potential. The RT300 cycle is used in leading clinics worldwide including all of the NeuroRecovery Network sites and can be used by children and adults in their homes. The company offers a dedicated team of experienced reimbursement specialists and this service is free.

Sigmedics, Inc. Parastep® I System

http://www.sigmedics.com/TheParastep http://www.sigmedics.com/announcements Phone: 212-729-1878 The Parastep is a microcomputer controlled functional neuromuscular stimulation (FNS) system that enables independent, unbraced ambulation (i.e., standing and walking) by people with a spinal cord injury. In 2014, Sigmedics donated the company to the Worldwide Alliance for Locomotion and Kinetics (WALK) of Merrick, NY.

Sigmedics: Questions and Answers about the Parastep System

http://www.sigmedics.com/faq

Therapeutic Alliances, Inc. (TAI)

http://www.ERGYS.com http://www.musclepower.com 333 North Broad St. Fairborn, OH 45324 Phone: 937-879-0734 Email: info@ERGYS.com

Therapeutic Alliances, Inc. makes and markets the ERGYS 3 and supports the older REGYS bikes. TAI offers a complete line of electrotherapy and rehabilitation equipment for treating and managing stroke, SCI, TBI, MS, CP, and other neuromuscular disorders and diseases. Among these products are the ERGYS, REGYS, NeuroEDUCATOR, SpectraSTIM, NeuroSwitch, and Parastep.

FES Information:

Cleveland FES Center

http://fescenter.org 10701 East Boulevard

Cleveland OH 44106 Phone: 216-231-3257

The Functional Electrical Stimulation Center was founded in 1991 to introduce FES into clinical practice. Their challenge is to translate fundamental knowledge of electrical stimulation of paralyzed nerves and muscles into useful systems that enhanced the independence and quality of life for people with disabilities. They advance toward this goal by integrating and facilitating the efforts of scientists, engineers, and clinicians across the institutional partners. Their website offers a comprehensive list of clinical trials of FES that would be of interest to those living with spinal cord injury, cerebral palsy, stroke, and traumatic brain injury.

Institute of Spinal Cord Injury, Iceland: Functional Electrical Stimulation

http://www.sci-therapies.info/FES.htm

(Note: Re section no. 5--Vocare is no longer available in the U.S.)

International FES Society (IFESS)

www.ifess.org

IFESS' mission is to promote the research, application, and understanding of electrical stimulation as it is utilized in the field of medicine through meetings, tutorials, publications, and the exchange of information.

MS Trust: FES

https://www.mstrust.org.uk/a-z/functional-electrical-stimulation-fes

National Multiple Sclerosis Society: FES

http://www.nationalmssociety.org/Treating-MS/Rehabilitation/Functional-Electrical-Stimulation-(FES)

Holicky, Richard. "E-stim for Wellness" New Mobility Sept. 2013.

http://www.newmobility.com/2013/09/e-stim-for-wellness/

Maddox, Sam. "FES Comes of Age". *New Mobility* June 2006, pp. 46-49, 66. Print article.

Gait Training

Gait Training refers to a kind of therapy that can help improve the ability to stand and walk (also called ambulation); it is often paired with assistive devices such as parallel bars, braces, orthoses, or walkers. It may or may not refer to being supported by a device over a treadmill. Please see the next section for more on treadmill training or locomotor training.

Model Systems Knowledge Translation Center: Spinal Cord Injury and Gait Training

http://www.msktc.org/sci/factsheets/Gait-Training-and-SCI

http://www.msktc.org/sci/slideshows/Gait-Training-After-Spinal-Cord-Injury

MSKTC is a national center that works to put research into practice to serve the needs of people with traumatic brain injuries, spinal cord injuries, and burn injuries.



Locomotor or Treadmill Training

Figure 3:LokomatPro in use Picture: Hocoma, Switzerland.

Locomotor training is a rehabilitation approach that has emerged from several decades of rigorous basic science research in laboratories in the U.S., Canada and Europe. It involves a kind of activity-triggered learning whereby practicing a series of specific movements (in this case, stepping) triggers the sensory information that somehow reminds the spinal cord how to initiate stepping. It is also known as treadmill training or weight-supported ambulation.

Treadmill training uses repetitive motion (in this case, moving the legs) to stimulate a walking pattern. A paralyzed person is suspended in a harness above a treadmill; this reduces the weight the legs will have to bear. As the treadmill begins to move, therapists move the person's legs in a walking pattern. The theory that drives the work is that paralysis causes "learned non-use" of muscles. But the injured nervous system is "plastic," that is, capable of recovery when certain conditions, including the patterned neural activity that accompanies treadmill walking, are optimized.

Research from the University of California at Los Angeles and in Germany, Switzerland and Canada, notes that the spinal cord contains nerve circuitry that is comparable to a brain; given the right sensory information, the spinal cord is smart and can interpret and execute on that information. The spinal cord makes many routine decisions about the correct way to walk. When a paralyzed person is retrained to walk, both the brain and spinal cord figure out new ways to do so.

In 2004, the Reeve Foundation launched the NeuroRecovery Network (NRN) to deploy locomotor training to individuals living with spinal cord injury and paralysis. Recent findings from the NRN suggest that there may be improvements in sitting, standing, reaching, balance or walking. Some participants may experience improved muscle and bone strength, cardiovascular regulation, blood glucose levels, overall quality of life, and decreased spasticity. The level of recovery is different for each person, although almost all those with incomplete injuries showed gains.

It is important to understand, however, that locomotor training is an evolving intervention. Scientists, physicians and therapists are still learning the best way to train and which patients can benefit the most. While locomotor training is part of the rehab experience for many Europeans, it is not as widely available in the U.S. This is changing as the commercialization of the technology moves forward and NRN data is more widely disseminated.

As treadmill units filter out into the community, it is important for people to recognize that a locomotor training program must include highly trained therapists to work with patients. Maximizing a patient's ability to step after injury depends to a very large extent on the skill and precision with which the therapists deliver locomotor training. It is also important to understand that there are different approaches to this physical therapy. Gait training is not the same thing as locomotor training and manual locomotor training is very different from training done using robotics.

Locomotor or treadmill training resources:

The following are a list of websites of manufacturers and vendors who provide locomotor training systems and related products. Please note a listing here is not an endorsement; the sites below are offered for informational purposes only.

Encompass Health (formerly HealthSouth)

https://www.encompasshealth.com/inpatient-rehabilitation/irf-our-

technology/autoambulator

9001 Liberty Parkway Birmingham, AL 35242

Phone: 800-765-4772

Encompass Health, is a large rehab center chain. In 2001, they introduced the **AutoAmbulator**, a harness and treadmill rig featuring a body weight supported ambulation designed to help patients safely relearn natural walking patterns.

Hocoma USA

http://www.hocoma.com/products/lokomat/

77 Accord Park Dr., Suite D-1 Norwell, MA 02061 Toll-free: 877 944 2200 Email: info.usa@hocoma.com

The **Lokomat**, from Switzerland, has been available in the U.S. since 2007. The device is described as an exoskeleton (an external skeleton) with robotic joints at the hip and knee to guide the user's legs as they step along the treadmill. The technology is intended to reduce the need for some of the therapists during a training session. Hocoma offers a guideline for using the Lokomat in children with cerebral palsy. Their research shows Lokomat training can be conducted safely and effectively with people with spinal cord injury, brain injury, Guillain-Barre Syndrome, stroke, cerebral palsy, and Multiple Sclerosis.

Mobility Research

http://www.litegait.com PO Box 3141 Tempe AZ, 85280

Toll-free: 800-332-WALK (9255)

Mobility Research sells a harness and treadmill training set up. The **LiteGait** system can be purchased directly for about \$10,500 with entry level models starting at under \$8,000 (the pediatric model starts at less than \$2,500) plus the treadmill, at \$2950. The company says it has many stories of paralyzed users getting function back. Its treadmill trainers are available around the U.S.

Power NeuroRecovery

https://powerneurorecovery.com/

312 Production Ct. Louisville, KY 40299 Power NeuroRecovery is the manufacturer of the **PowerStep** locomotor training system.

For more detail on clinical trials see <u>http://clinicaltrials.gov</u> -- type the word "treadmill" in the search box.

Locomotor Training Articles:

"Body Weight Supported Treadmill Training". *SCI Update* Spring 2003 http://sci.washington.edu/info/newsletters/articles/03sp_body_weight_support.asp

"Locomotor Training: As a Treatment of Spinal Cord Injury and in the Progression of Neurologic Rehabilitation" *Archives of Physical Medicine and Rehabilitation* Sept 2012. The Sept. 2012 supplement of APMR had multiple articles devoted to the Reeve Foundation's NRN.

http://www.archives-pmr.org/article/S0003-9993(12)00398-X/fulltext

Christopher & Dana Reeve Foundation's NeuroRecovery Network (NRN)

The endgame for the Reeve Foundation is to translate discovery scientific findings to the clinic and to that end, the Foundation created the NeuroRecovery Network (NRN) in 2004. The NRN is a cooperative network of cutting-edge rehabilitation centers and community fitness and wellness gyms designed to provide and develop evidence-based interventions that promote functional recovery and improve the health and quality of life for people living with paralysis.

The initial treatment offered was Locomotor Training using body weight support on a treadmill. In this form of rehabilitation, patients are hoisted over treadmills and helped to move their feet in stepping motions. Over time, as they repeat the stepping movements again and again and gradually bear more weight, their spinal cords below the injury level seem to reawaken and activate the leg and foot muscles involved in walking and standing. Outcomes from more than 1,000 NRN participants highlight success stories from the NRN and confirm that Locomotor Training supports recovery and improved NeuroRecovery health. For more detail the Network. please visit on https://www.christopherreeve.org/research/our-rehabilitation-network or call 800-225-0292 for a brochure.

To apply to become a patient of the NeuroRecovery Network, please click on the link below of the center(s) where you'd like to receive therapy. (*note: please fill out a form* for <u>each center</u> you're interested in applying to). <u>https://www.christopherreeve.org/research/our-rehabilitation-network/nrn-clinicalcenters</u>

Reeve Foundation NRN Centers for Adults:

- Craig Hospital, Englewood, CO
 Phone: 303-789-8127
 Candy Tefertiller, Email: <u>ctefertiller@craighospital.org</u>
- Frazier Rehab Institute, Louisville, KY http://www.christopherreeve.org/site/lookup.asp?c=ddJFKRNoFiG&b=4474157 Phone: 502-582-4715 or 1-866-540-7719 Kimberly N. Atkinson, Email: http://www.christopherreeve.org/site/lookup.asp?c=ddJFKRNoFiG&b=4474157 Phone: 502-582-4715 or 1-866-540-7719 Kimberly N. Atkinson, Email: https://www.christopherreeve.org/site/lookup.asp?c=ddJFKRNoFiG&b=4474157 Phone: 502-582-4715 or 1-866-540-7719

- Kessler Institute For Rehabilitation, West Orange, NJ <u>http://www.christopherreeve.org/site/lookup.asp?c=ddJFKRNoFiG&b=4474173</u> Phone: 973-731-3600 Gail Forrest, Email: gforrest@kesslerfoundation.org
- Magee Rehabilitation Hospital, Philadelphia, PA <u>http://www.christopherreeve.org/site/lookup.asp?c=ddJFKRNoFiG&b=4771367</u> Phone: 215-218-3900 Mary Schmidt Read, Email: <u>mschmidt@mageerehab.org</u>
- Ohio State University Medical Center, Columbus, OH <u>http://www.christopherreeve.org/site/lookup.asp?c=ddJFKRNoFiG&b=4474175</u> Phone: 614-293-9717
 D. Michele Basso, Email: <u>Basso2@osu.edu</u>

Reeve Foundation NRN Pediatric Centers:

- Frazier Rehab Institute, Louisville, KY http://www.christopherreeve.org/site/lookup.asp?c=ddJFKRNoFiG&b=4474157 Phone: 502-582-4715 or 1-866-540-7719 Miranda Garvin, Email: mirandagarvin@kentuckyonehealth.org
- Children's Hospital of Pittsburgh of UPMC, Pittsburgh PA <u>http://www.chp.edu/</u>

Reeve Foundation Community Fitness and Wellness Facilities:

- Courage Kenny Rehabilitation Institute, Minneapolis, MN http://www.couragecenter.org/ Phone: 612-775-2200 Contact CKRIABLE@allina.com
- Frazier Rehab Institute, Louisville, KY <u>https://uoflhealth.org/locations/frazier-rehabilitation-institute/</u> Phone: 502-582-7411 Contact Karey McDowell at <u>Karey.McDowell@jhsmh.org</u>. <u>http://www.christopherreeve.org/atf/cf/%7B3d83418f-</u> <u>b967-4c18-8ada-adc2e5355071%7D/FRAZIER CFW APP_2010.PDF</u>
- Journey Forward, Canton, MA <u>http://www.journey-forward.org/</u> Phone: 781-828-3233
- NextSteps Chicago, Willow Springs, IL <u>http://www.nextstepschicago.org/</u> Phone: 708-467-0657 Contact nextstepschicago@gmail.com

- NextStep Fitness, Lawndale, CA <u>http://www.nextstepfitness.org/</u> Phone: 310-546-5666 Contact Janne Kouri, jannek@nextstepfitness.org
- NeuroHope Indianapolis, IN
 <u>https://www.neurohopewellness.org/</u>
 Phone: 317-525-8386
- NeuroKinex, Gatwick UK
 <u>http://neurokinex.org/</u>
 Contact: info@neurokinex.org

On Demand Video

YouTube: NextStep Story

https://www.youtube.com/watch?v=1JHETOsrWY0

NextStep is a Reeve NRN Community Fitness and Wellness center. The clip features Janne Kouri, founder of NextStep, Peter Wilderotter, President and CEO of the Reeve Foundation, and the Reeve Foundation's VP of Research, Susan Howley.

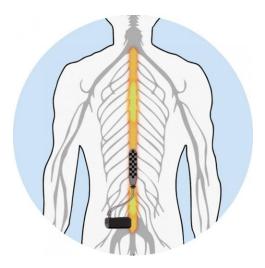
Neuromuscular Electrical Stimulation (NMES)

The latest intervention being deployed by the Reeve Foundation's NeuroRecovery Network (NRN) is neuromuscular electrical stimulation (NMES). NMES involves a revised take on FES which has been used for many years to activate the muscular system. However, NMES does not teach or re-train the system like Locomotor Training does. Instead, NMES stimulates access to the central nervous system, heightening the system's excitability and increasing motor output.

NeuroMuscular Electrical Stimulation (NMES) was introduced to the NRN in 2014. NMES in the NRN has been used with the upper extremities and trunk to increase appropriate kinematics of movements and to excite the central nervous system and improve neuroplasticity for the upper extremities. NMES use for the lower extremities is gradually being rolled out to the sites as training and necessary equipment is available. The NMES upper extremity intervention was implemented at both the clinical rehab centers and the community fitness and wellness facilities of the NRN.

University of Louisville's Kentucky Spinal Cord Injury Research Center: NMES https://victoryoverparalysis.org/neuromuscular-electrical-stimulation/

Epidural Stimulation



Epidural stimulation is the application of a continuous electrical current, at varying frequencies and intensities, to specific locations on the lumbar spinal cord using a stimulator implanted over the dura. The dura is the outermost layer of the membrane system that surrounds the spinal cord. The stimulator is controlled by a remote about the size of a smartphone.

Epidural stimulation is being used to activate the nerve circuits in the spinal cord to provide signals that would normally come from the brain. It is believed that epidural stimulation raises the level of excitability of the nerve networks in the spinal cord. There are many debilitating, life-threatening dysfunctions associated with spinal cord injury, including poor cardiovascular and respiratory function, loss of bladder and sexual function, skin breakdowns, and body temperature and blood pressure irregularities. Early studies in humans suggest that epidural stimulation may improve autonomic system function and lessen some of these secondary dysfunctions.

In 2011, the Reeve Foundation partially funded an epidural stimulation study at the University of Louisville that produced groundbreaking results. Rob Summers, a young man who was injured at the C7/T1 level five years before, had an epidural stimulator surgically placed over his lumbar spinal cord. When the stimulator was activated, Summers was able to rise from his chair, fully bear his weight, and stand unassisted. The epidural stimulation did not directly affect his leg muscles; it activated nerve circuits of the spinal cord not controlled by the brain. He was able to animate his lower extremities because the stimulation made the spinal cord more sensitive to sensory cues. Summers also had functional gains in bladder control, sexual function, blood pressure and temperature regulation.

Three more people living with quadriplegia were implanted and demonstrated nearly identical results to Summers. The Reeve Foundation has continued to support this study with a clinical trial of 36 more people living with spinal cord injury that will soon begin at the University of Louisville.

In short, the scientists have uncovered a new intervention strategy that may dramatically affect recovery of voluntary movement, health and quality of life in individuals with complete paralysis even years after their injury.

Resources for epidural stimulation:

Christopher & Dana Reeve Foundation: The Big Idea

https://www.reevebigidea.org/

The Reeve Foundation's campaign, "The Big Idea" continues to raise money to support a clinical trial in epidural stimulation. There is a lot of information here on the first four men who underwent the epidural stimulator implant and their progress. There is also information on epidural stimulation in general.

The Promise of Epidural Stimulation. By Kate Willette New Mobility April 2018.

http://www.newmobility.com/2018/04/the-promise-of-epidural-stimuilation/

University of Louisville: Victory over Paralysis

https://victoryoverparalysis.org/participate-in-research

This site offers a registry to sign up for the epidural stimulation clinical trial. The Reeve Foundation does not control enrollment in the trial and enrollment does not constitute acceptance into the trial.

Transcutaneous Stimulation

In 2015, a team of researchers led by UCLA's Dr. V. Reggie Edgerton and Dr. Yury Gerasimenko made news when five men with complete motor paralysis were able to voluntarily generate step-like movements. The study, funded in part by the National Institutes of Health and the Reeve Foundation among others, used transcutaneous stimulation to achieve those results. Transcutaneous stimulation is a non-invasive intervention in which electrodes are strategically placed on the skin near the spinal cord to deliver electrical stimulation. In this study the men's movements took place while their legs were suspended in braces from the ceiling so that there was no resistance to gravity. This could mean that a potentially life changing therapy, one without surgery or the higher cost of an implanted stimulator, might be effective for some who live with paralysis from SCI or other neurological disorders.

Edgerton has initiated studies to see if the same men can bear their own weight while not supported and hopes to study whether non-invasive stimulation can help people with paralysis regain some functions such as temperature regulation, blood pressure regulation, and better control of bowel, bladder and sexual function.

Resources for Transcutaneous Stimulation

UCLA Press Release: In UCLA study, non-surgical approach helps people with paralysis voluntarily move their legs – a first <u>http://newsroom.ucla.edu/releases/in-ucla-study-non-surgical-approach-helps-people-</u>

with-paralysis-voluntarily-move-their-legs-a-first

General Neurorecovery or Neurotechnology Resources:

National Center for Advancing Translational Sciences (NCATS)

www.ncats.nih.gov

NCATS focuses on developing and disseminating improvements in translational science that brings about tangible improvements in human health.

GTX Medical

https://www.gtxmedical.com/

GTX is a medical device company focusing on the development of a unique neurostimulation therapy. GTX Medical was formed by a merger of NeuroRecovery Technologies (NRT) and GTX Medical BV. NRT was a medical technology company focused on the design and development of devices to help restore function and movement in people with paralysis. The current technology evolved from collaborative research between UCLA, The California Institute of Technology, and the University of Louisville. The merged company is developing Targeted Epidural Spine Stimulation (TESS), an implantable spinal cord stimulation system.

Neurotech Network

http://www.neurotechnetwork.org/

P.O. Box 16776 St. Petersburg, FL 33733 Phone: 727-321-0150 Email: <u>info@neurotechnetwork.org</u>

Neurotech Network is a non-profit organization dedicated to improving the education of and advocacy for access to neurotechnology for people with neurological impairments.

Exoskeletons

Exoskeletons and the role they are playing in both the rehabilitative care and home life of people living with paralysis became an important emerging technology in 2014. Several exoskeleton walking devices are coming to market for people with paralysis. These are battery powered bionic legs with small motors on the joints.

In June 2014, the Food and Drug Administration (FDA) approved the ReWalk Personal System for use in the home and in the community. It was the first exoskeleton device to be approved by the FDA. According to the company, the system: "Provides userinitiated mobility through the integration of a wearable brace support, a computer-based control system, and motion sensors." ReWalk affords people living with paraplegia with the opportunity to both stand and walk independently, but the cost could be prohibitive for some 2014 Slate article а (http://www.slate.com/blogs/future tense/2014/07/02/rewalk exoskeleton approved by <u>_fda_but_who_will_pay_for_it.html</u>.) claimed the price of owning one of these devices is close to \$70,000. ReWalk comes from Israel and Europe. Rewalk has become Lifeward.

Ekso Bionics received FDA approval in April 2016 for its Ekso GT. It was approved to market its Ekso GT robotic exoskeleton for use in the treatment of individuals with hemiplegia due to stroke, individuals with spinal cord injuries at levels T4 to L5, and individuals with spinal cord injuries at levels of T3 to C7 (ASIA D). The Ekso GT is the

first exoskeleton cleared by the FDA for use with stroke patients. According to the company, the device is intended for supervised use in a clinical setting by individuals with various levels of paralysis. Ekso's reported findings, from September 2012, were culled from a clinical trial of 13 individuals, 12 with paraplegia, and one with tetraplegia. The study found that walking and standing in Ekso's device was feasible, and that improvements in function were made by training with the device: Walking speed and distance, fluidity, gait, and balance all got better, the company says.

The Parker Indego (<u>http://www.indego.com/indego/en/research</u>.) is a "powered lower limb orthosis enabling people with mobility impairments to walk and participate in over-ground gait training." The Indego is still in early phases of clinical testing: In July 2014, the company tested the device at the Shepherd Center in Atlanta, Georgia – it was the first time that it had ever been used by an individual living with quadriplegia - Cole Sydnor. The Indego devices are not currently approved for personal use in the U.S.

The Hybrid Assistive Limb (HAL), developed by Japanese robot maker Cyberdyne, is moving through the medical device approval processes.

The companies suggest exoskeleton devices will do more than give users eye-to-eye contact with others. Health benefits may include better bone density and reduced pain. There is anecdotal evidence that robotic walking helps bowel and bladder function.

As of January 1, 2024, Medicare will cover certain types of exoskeletons. The Centers for Medicare & Medicaid Services ("CMS") finalized the Calendar Year 2024 Home Health Prospective Payment System Rule CMS-1780 ("2024 Home Health Rule") which reclassified certain exoskeletons, making them eligible for payment under the brace category.

Sources: Paralysis Resource Guide 2013; Ekso Bionics press release 4/4/16, Centers for Medicare and Medicaid <u>fact sheet</u> 11/1/23

Websites

Christopher & Dana Reeve Foundation Research Blog: Keeping the X in Exo April 2016

https://www.christopherreeve.org/blog/research-news/keeping-the-x-in-exo

The following are a list of websites of manufacturers and vendors who provide exoskeleton systems and related products. Please note a listing here is not an endorsement; the sites below are offered for informational purposes only.

Ekso Bionics www.eksobionics.com

1414 Harbour Way South, Suite 1201 Richmond, CA 94804 Phone: 510-984-1761

Email: CustomerRelations@eksobionics.com

Cyberdyne's Hybrid Assistive Limb

www.cyberdyne.jp/english 2-2-1, Gakuen-Minami, Tsukuba Ibaraki Prefecture, 305-0818, Japan

Lifeward (formerly ReWalk Robotics) (US office) https://golifeward.com/ 200 Donald Lynch Blvd. Marlborough, MA 01752 Phone: 508-251-1154 Email: contact@golifeward.com

Parker Hannifin's Indego

http://www.indego.com Phone: 844-846-3346 Email: <u>c-parker@parker.com</u>

There are some other types of rehabilitation interventions or therapies not covered here. If you want to keep up with the latest in research, please visit the Reeve Foundation's research web pages at <u>www.ChristopherReeve.org/Research</u>. Please also note the Reeve Foundation's stance (<u>https://www.christopherreeve.org/blog/daily-dose/caution-the-possible-dangers-of-offshore-epidural-stimulation-treatments</u>.) on having epidural stimulation done outside of the United States where there may not be the same patient safety controls and regulations as the United States has under the Food and Drug Administration. The same cautions should apply to any of the other interventions and therapies mentioned here.

The information contained in this message is presented for the purpose of educating and informing you about paralysis and its effects. Nothing contained in this message should be construed nor is intended to be used for medical diagnosis or treatment. It should not be used in place of the advice of your physician or other qualified health care provider. Should you have any health care related questions, please call or see your physician or other qualified health care provider before embarking on a new treatment, diet or fitness program. You should never disregard medical advice or delay in seeking it because of something you have read in this message.

This publication is supported by the Administration for Community Living (ACL), U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling \$10,000,000 with 100 percent funding by ACL/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by ACL/HHS, or the U.S. Government.