

# Rehabilitation Interventions and Therapies



Figure 1:A male undergoing Locomotor Training with two people attending him.

Research conducted over the past few decades increasingly demonstrates the importance of physical rehabilitation for improving function and quality of life after a spinal cord injury. Intensive, activity-based training, including robotic and body-weight support treadmill training, and overground and standing training can help reorganize and reactivate dormant nerve circuits, leading to gains in mobility and autonomic function. Scientists continue to study how physiological changes in the nervous system are fostered by high-intensity training compared to standard rehabilitation programs. Activity-based training in combination with advanced therapeutic technologies such as electrical stimulation has also become a central focus of current spinal cord injury research. The purpose of electrical stimulation - deployed through electrodes placed on the skin's surface or through surgical implantation over the spinal cord - is to replicate signals sent by the brain along the spinal cord prior to injury; in this treatment, electrical pulses activate neural circuits and cause muscle contraction. The use of electrical stimulation on its own and in combination with activity-based training has yielded multiple gains in mobility and autonomic function for individuals with chronic injury and remains a potentially crucial component of future treatments for paralysis.: Almost any treatment to restore function after paralysis will require a physical component to rebuild muscle, rebuild bone, and reactivate patterns of movement. Some form of rehabilitation training will be needed even after function comes back.

Stepping during treadmill training sends sensory information to the locomotor central pattern generator (CPG), adapting and reinforcing the circuits necessary for stepping. Scientists use the term plasticity to describe this reinforcement—the nervous system is not "hard wired" and appears to have the ability to change in response to new stimulation. Researchers are learning much more about the exact role of sensory information within the CPG and ways to increase the ability of the spinal cord to learn (or relearn) new tasks.

While rehabilitation techniques are still improving, they evolved to the point that exercise and physical activity are an essential component of recovery. The amount and intensity of activity-based training seems to play a large role in the amount of functional recovery an individual experiences. For the person with a spinal cord injury, it's best to stay active and always strive for the maximum outcome.

The following interventions will be discussed below:

- Locomotor and 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 restore function and improve overall health and 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 participating in advanced rehabilitation therapies, such as FES or treadmill or locomotor 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

After his accident, Christopher Reeve recovered some movement and sensation. While he was not able to walk, did not regain bowel, bladder, or sexual function, his limited recovery was 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. While his recovery may have been related to exercise, Dr. McDonald and other researchers and clinicians caution not to over-interpret Reeve's results as 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."

\*High quad refers to a person who was spinal cord injured in the cervical region (C1-C8); Reeve was injured in the C1/C2 vertebrae of the spine.

# **Functional Electrical Stimulation (FES)**



Figure 2:Photo Courtesy of Chanda Plan. A male using an FES bike is pictured.

This technology allows people 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., Restorative Therapies, which has a bike that can be used by children as young as four years old and MYOLYN which produces the easy-to-use MyoCycle, available both in-clinic and for at-home use. 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 (<a href="www.carf.org">www.carf.org</a>) and find a rehab center in your area that specializes in your diagnosis (SCI, etc.) and then

contact them to see if they offer it. Alternatively, you can reach out to home use manufacturers to pursue a personal unit.

#### **FES Resources**

The following is 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\_lt.php

#### **MYOLYN**

https://myolyn.com 6931 NW 22<sup>nd</sup> St., Suite A Gainesville, FL 32653 Phone: 352-306-8431

Email: myolyn@myolyn.com

The MyoCycle Home FES bike was designed to make FES technology accessible to everyone who needs it. MYOLYN provides personalized funding assistance and will work with you one-on-one to give you all the information and resources needed to obtain your own MyoCycle Home FES Cycling System.

#### **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 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

https://www.sigmedics.com/parastep-i-system https://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** https://www.sigmedics.com/fag

#### **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 (also called locomotor 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, orthotics (also known as orthoses), crutches, 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.

# 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 and 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 reminds the spinal cord how to initiate stepping.

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. 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.

As treadmill units become more common in 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 and treadmill training resources:**

The following is 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.

#### 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 <a href="http://clinicaltrials.gov">http://clinicaltrials.gov</a> -- 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

#### On Demand Video

YouTube: NextStep Story

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

NextStep is a 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 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 the early 2000's, the Reeve Foundation identified epidural stimulation as a highly promising area of research. As the science took shape, and with the Foundation's

unique expertise in critical aspects of the field – technology, regulatory, market opportunity, IP and costs – it became a leading investor, providing end-to-end support for this scientific approach.

Reeve-funded lab work at the University of California, Los Angeles and, later, at the University of Louisville, led to the creation of an early-stage biotech called NRT (with the Reeve Foundation serving as an early investor). Through several evolutions, NRT became what is known today as ONWARD Medical N.V., a medical technology company creating innovative therapies to restore movement, independence, and health in people with spinal cord injury.

ONWARD has been awarded numerous Breakthrough Device Designations, highlighting the company's innovative approach to developing therapies for people with SCI, and the company is received FDA approval of its first product – ARC<sup>EX</sup> -- in 2024.

ARC<sup>EX</sup> is an investigational spinal cord stimulation system that targets areas of injury on the spinal cord with programmed electrical pulses through the skin. The non-invasive system is designed to improve the strength, sensation, and function necessary to restore movement and independence after spinal cord injury.

In 2024, ONWARD announced findings from its ARC<sup>EX</sup> Up-LIFT pivotal trial, published in *Nature Medicine*. Up-LIFT achieved all primary safety and effectiveness endpoints and showed significant improvements in upper limb strength, function and sensation among those with chronic tetraplegia due to cervical SCI. Up-LIFT findings include:

- 72% of trial participants were considered responders to non-invasive ARC-EX therapy. Investigators based this designation on a conservative definition requiring responders to meet improvement criteria in both strength and functional domains vs. standard of care rehabilitation alone.
- The number of responders increased to 90% when the definition included participants with improvements in at least one strength or functional outcome.
- Participants also reported reduced spasm frequency, improved sleep and improved upper body sensation, including the sense of touch.
- 87% of participants reported that ARC<sup>EX</sup> therapy delivered improvements in overall quality of life. Self-care, a key component of independence after SCI, also improved significantly.

ONWARD's devices are among the most eagerly awaited med-tech breakthroughs of recent years. The Reeve Foundation's support in ONWARD continues through SCI Ventures, the first venture philanthropy fund for SCI, co-founded by the Foundation. The evolving Reeve-ONWARD partnership represents a modern approach for nonprofit-industry partnership.

Today, the Reeve Foundation's support for ongoing research in this area includes a \$1.1 million grant investigating ONWARD's ARC-BCI (Brain-Computer Interface) System. Specifically, this grant supports four clinical trial participants to be implanted with the BCI system. The early feasibility study evaluates the use of BCI to restore the thought-driven use of the hands and arms after SCI. The first participant in the study received their investigational ARC-BCI implant in August 2023.

Additionally, Reeve Foundation funding to NeuroRestore – a research, innovation and treatment center developing bioengineering strategies involving neurosurgical interventions and ONWARD's research partner – is enabling investigation of epidural stimulation as a potential tool for managing bladder dysfunction, a significant quality-of-life issue for the SCI community.

#### Resources for epidural stimulation:

Powell MP, Verma N, Sorensen E. et al. Epidural Stimulation of the Cervical Spinal Cord for Post-Stroke Upper-Limb Paresis. Nature 20 February 2023. https://www.nature.com/articles/s41591-022-02202-6

The Promise of Epidural Stimulation. By Kate Willette New Mobility April 2018. <a href="http://www.newmobility.com/2018/04/the-promise-of-epidural-stimuilation/">http://www.newmobility.com/2018/04/the-promise-of-epidural-stimuilation/</a>

#### **University of Louisville: Victory over Paralysis**

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

This site offers information on how to sign up for University of Louisville epidural stimulation clinical trials. For more on the University of Louisville Epidural Stimulation Program, see: <a href="https://victoryoverparalysis.org/research/translational-research/epidural-stim-pgm/">https://victoryoverparalysis.org/research/translational-research/epidural-stim-pgm/</a>.

# **Transcutaneous Stimulation**

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 Dec. 2024, the Food and Drug Administration approved Onward Medical's ARC-EX system as the first and only technology proven to improve hand strength and sensation after chronic spinal cord injury. The ARC-EX system is intended to deliver transcutaneous electrical spinal cord stimulation in conjunction with functional task practice to improve hand sensation and strength in individuals between 18 and 75 years of age that have a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury (C2-C8 inclusive).

#### **Resources for Transcutaneous Stimulation**

#### **ONWARD Medical**

https://www.onwd.com

Based in the Netherlands, ONWARD creates therapies that stimulate the spinal cord. The Christopher & Dana Reeve Foundation is a partner and shareholder in ONWARD. They developed the ARC-EX system. Questions about it can be sent to them using this form: <a href="https://survey.onwd.com/support">https://survey.onwd.com/support</a>. This link is not a survey even though the word is in the URL. It is a link to get in touch with Onward about ARC-EX.

Moritz, C, et al. Non-Invasive Spinal Cord Stimulation for Arm and Hand Function in Chronic Tetraplegia: A Safety and Efficacy Trial. *Nature Medicine*. 2024. This article has information about the Up-LIFT clinical trial on ARC-EX.

# **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.

#### **Neurotech Network**

http://www.neurotechnetwork.org/

P.O. Box 16776

St. Petersburg, FL 33733 Phone: 727-321-0150

Email: info@neurotechnetwork.org

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**

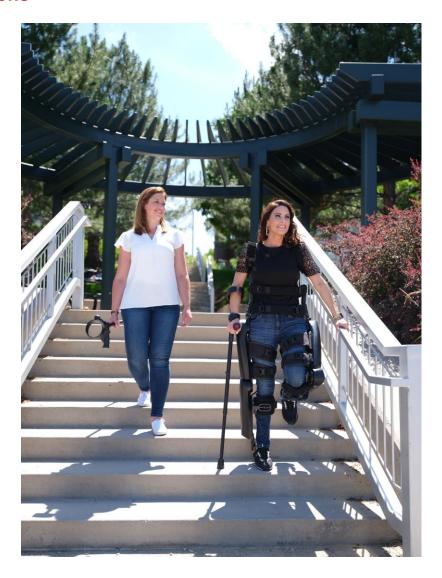


Figure 5: Female using Lifeward exoskeleton on stairs, Photo Courtesy of Lifeward

Exoskeletons – wearable, battery-powered brace supports with motion sensors and computer-based controls – can play an important role in the rehabilitative care and daily life of people living with paralysis.

Introduced in healthcare settings in 2011, exoskeleton-assisted walking is used for gait training and to help mitigate secondary complications related to spinal cord injury; potential health benefits include reduced pain and spasticity, as well as improved bowel and bladder function. Devices including the Hybrid Assistive Limb (HAL) by Cyberdyne, and the Ekso GT, the first exoskeleton approved for use with stroke patients, may be part of your local spinal cord injury rehabilitation hospital or in Veterans Affairs facilities. In 2014, the ReWalk Personal System became the first exoskeleton to be cleared for use in home and community settings by the Food and Drug Administration.



Figure 6: Male using Ekso Indego exoskeleton, Photo Courtesy of Ekso Bionics

In January 2024, 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; currently, the Ekso Indego and ReWalk Personal System are the only devices approved for home and community use; each may be covered for medically eligible individuals.

Sources: Paralysis Resource Guide; Lifeward, Ekso Bionics, Centers for Medicare and Medicaid fact sheet (https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2024-home-health-prospective-payment-system-final-rule-cms-1780-f) 11/1/23

#### Websites

The following is 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

101 Glacier Point, Suite A San Rafael, CA 94901 Phone: 510-984-1761

Email: <u>CustomerRelations@eksobionics.com</u>

#### 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

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 <a href="www.ChristopherReeve.org/Research">www.ChristopherReeve.org/Research</a>. Please also note the Reeve Foundation's stance (<a href="https://www.christopherreeve.org/blog/daily-dose/caution-the-possible-dangers-of-offshore-epidural-stimulation-treatments">https://www.christopherreeve.org/blog/daily-dose/caution-the-possible-dangers-of-offshore-epidural-stimulation-treatments</a>.) 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 promptly. Always consult with 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.