

# Spinal Cord Injury: “Unproven” therapies vs clinical trials

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## **For the sake of clarity...**

- There is (not yet) a cure/ therapies available to reverse paralysis after complete spinal cord injury
- There will be, but it will take time and it will probably be incremental progress towards full recovery

# Spinal Cord Injury research is progressing



# A few key research directions



- **Neuro-protection:** (preventing further damage just after the lesion. This line of research exclusively applies to very recent injuries ("acute" SCI)
- **Scar reduction:** alleviating the scar is indispensable a few weeks after the lesion ("chronic" SCI). The use of various peptides (proteins) is investigated to reach that goal
- **Neuro-plasticity promotion:** creating new neural pathways to communicate messages from the brain to the various parts of the body.
- **Neuro-regeneration:** repairing or replacing the damaged nerves or neurons to enable connection. This can involve external factors like stem-cells, bio-materials, 3D bio-scaffold to guide regrowth, molecules to promote neural growth. This can also include intrinsic enhancement, e.g. through turning growth-inhibitors by using gene-therapies
- **Neuro-stimulation/ e-stim:** stimulating the spinal cord through electrodes, either through the skin (trans-cutaneous e-stim) or via a surgically-implanted e-stimulator. This serves as a neuro-prosthetic (activates the nerves through electricity, thereby generating targeted muscle activities) and/or as neuro-modulation to possibly awaken dormant nerves/connection (this part is limited). This should be seen as a targeted rehab method rather than a regeneration/ cure therapy.

For details about various pre-clinical (in the lab) & clinical (human trial) research projects, see our research overview latest update:  
<https://endparalysis.org/cure-spinal-cord-injury-latest-therapies-research-3-2/>

# All SCI curative therapies/ treatments are still **EXPERIMENTAL**



Scientifically  
driven clinical trials



Everything  
In-between



Unproven (for-profit)  
therapies

# “Unproven” therapies for SCI are broadly available on the market...



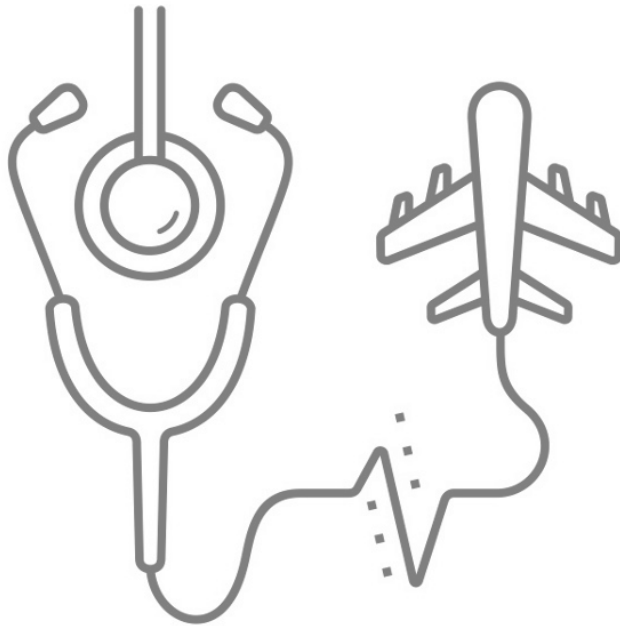
In countless  
exotic countries

## HOPE

Surf on SCI latest  
hyped research, e.g.:

- e-stimulation
- Stem-cells

# How do you recognize “Unproven” therapies?



- **Costly** (you will be charged for the cost, without any guarantee)
- commercially rather than scientifically-driven and possibly risky
- not transparent in terms of protocol and results (no publication)
- not approved by regulatory organizations and listed in [clinicaltrials.gov](https://clinicaltrials.gov)
- Heavily marketed via internet and social media
- Applied to a large range of conditions, from Alzheimer, to Erectile dysfunction and Aging!
- Mostly located in **exotic** places
- Often unethical



## A New Hope

Innovations in modern medical science has explored the latest technology through stem cells that can hold off major symptoms & aid healing. Multiple studies have shown that regenerative therapies can vastly improve the overall quality of life for various diseases previously thought to be incurable with traditional therapies.

Known as the 'Future of Medicine', **Stem Cells therapies** have changed the lives of thousands of patients suffering from a variety of diseases that traditional medicines could not help with. At [REDACTED], using cutting-edge research & technology, we have helped more

### Neurodisorders



ALS/MND



Autism



Parkinson



Cerebral Palsy



Muscular Dystrophy



Alzheimer



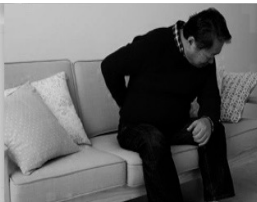
Multiple Sclerosis



Stroke



Spinal Cord Injury



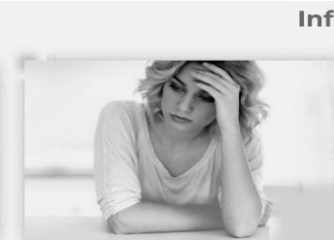
Ankylosing Spondylitis



Sports Injuries



Infertility



### Anti Aging



Anti Aging



Hair Loss



Look Fit



Feel Fit

Example



# "Unproven" therapies for SCI are not without risks!



Debilitating pain, tumour,  
infections...



Or worse

More info:

- [Glioproliferative Lesion of the Spinal Cord as a Complication of "Stem-Cell Tourism"](#)
- [A Comprehensive Analysis of Reported Adverse Events in Patients Receiving Unproven Stem Cell-Based Interventions](#)
- <https://www.pressreader.com/uk/the-sunday-telegraph/20120408/281492158293746>

# A relentless for profit approach: You stand to loose functions, and money!

Example

Company name: Cells4Health / XCELLS, by Mr Cees Cornelius Kleinbloesem

Course of events 2006- 2022:

- (2006) Cells4health sold treatment in Turkey
- At least 4 patients reported losing significant functions
- Cells4health had to leave Turkey and went to Azerbaijan.
- Unethical practice related by American patients
- Cells4health became Xcells
- (2007-2011) Xcells used a legal loophole in Germany and sold stemcells therapy there
- Baby died
- Xcells had to leave Germany
- Xcells started again in Libanon
- ...
- (2018?), Cells4health reappears on social media and sells stemcell therapies again in Europe! Numerous American patients go for it!
- One American patient is promised a surgery out of Bermuda. (2019). Loses his investment. See his post: on Oct. 12, 2019. <https://www.facebook.com/tjsdreamtowalkagain>
- 2022: Mr Kleinbloesem still makes money out of desperate patients: Cells4Health is now registered in Switzerland and has just become a technical partner of a brandnew stemcell company selling treatments for all imaginable conditions in India!

# On the other end, clinical trials are:

- **Free of charge** (you should NOT be charged for an experimental therapy!)
- Scientifically driven
- Transparent in terms of protocol & results
- Approved by regulatory organizations (e.g. FDA, EMA)
- Listed in [clinicaltrials.gov](https://clinicaltrials.gov) / [www.scitrials.org](https://www.scitrials.org)
- Adding up to global scientific knowledge & thereby **advancing progress towards curing SCI**



# “Everything in-between”: the grey area...



## Other human trials



These can be:

- Both commercially and scientifically-driven therapies (possibly listed on [clinicaltrials.gov](https://clinicaltrials.gov) but to be paid for),  
or
- Human trials driven by the SCI community, with the clear goal to accelerate the path to curing SCI, but taking place in exotic countries and not listed in registries



# Why do “unproven” therapies often “win” vs clinical trial?

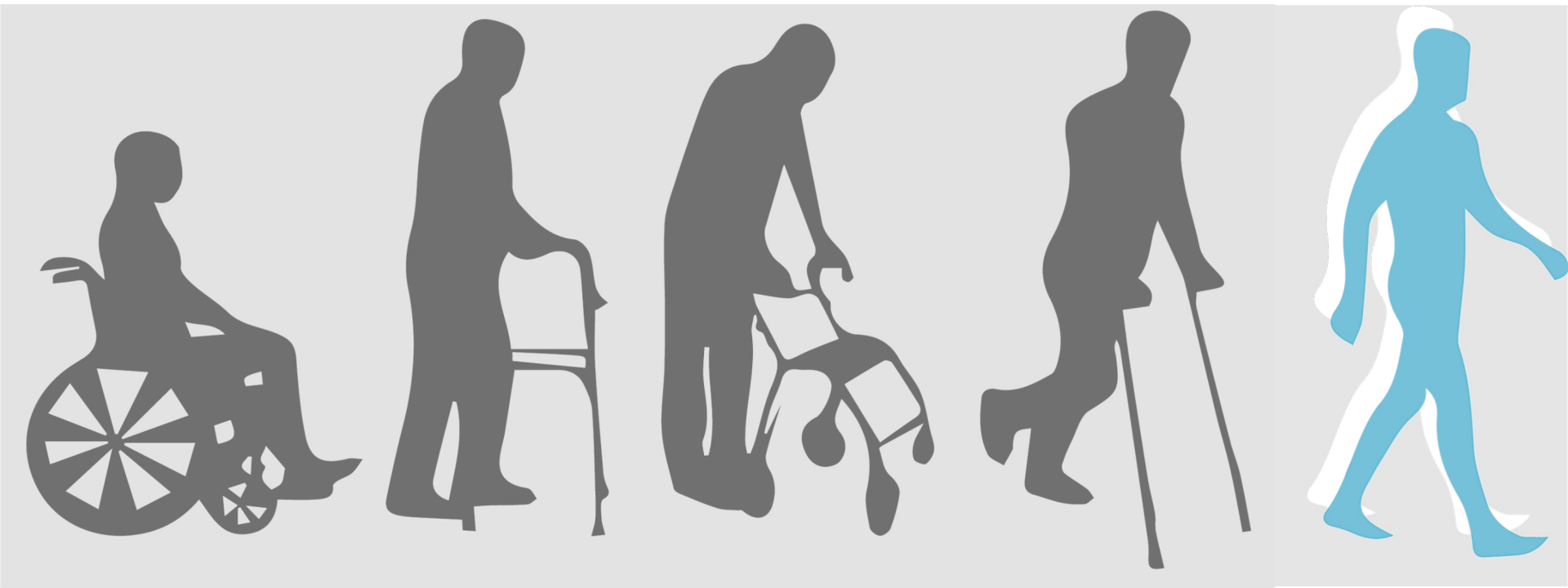


No guarantee, but...  
exiting story-telling  
on social media



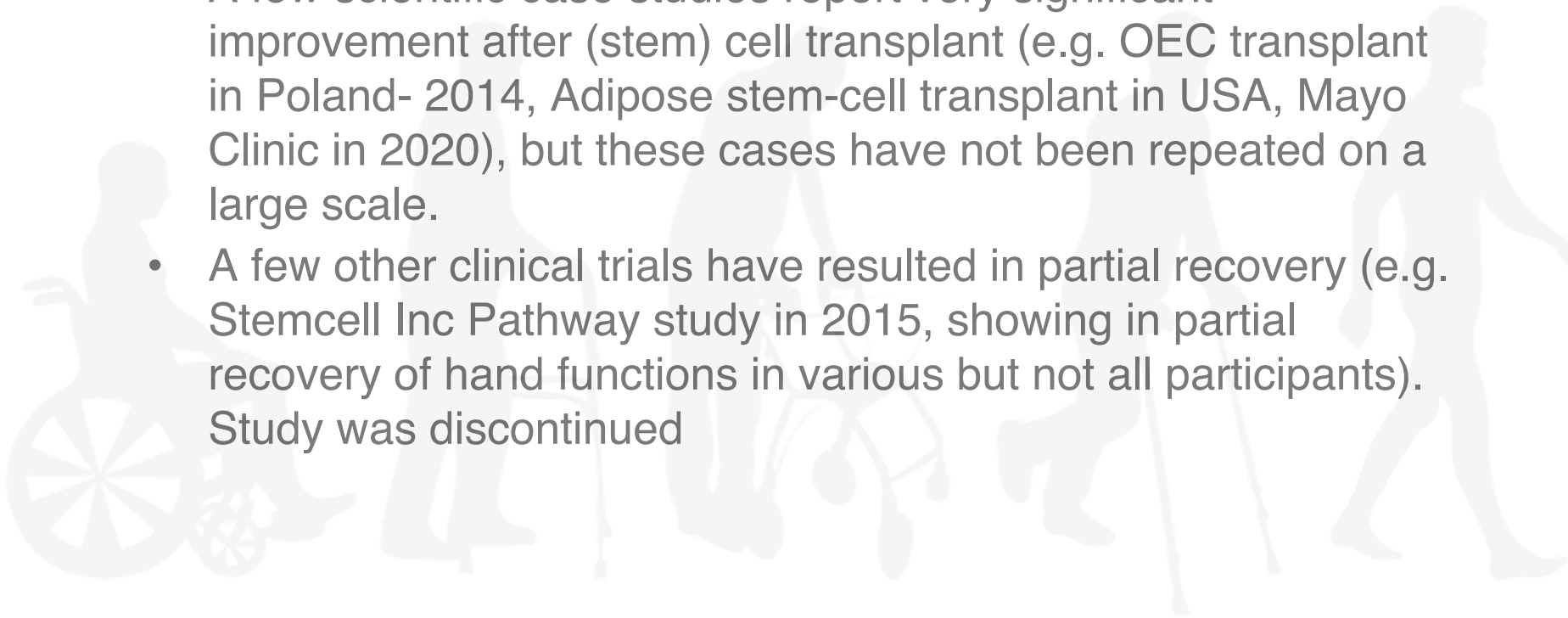
No waiting-time  
No endless list of  
selection criteria

# What are the results?



# Recovery level after cell transplant in clinical trials

- Results seem to be rather limited so far.
- A few scientific case studies report very significant improvement after (stem) cell transplant (e.g. OEC transplant in Poland- 2014, Adipose stem-cell transplant in USA, Mayo Clinic in 2020), but these cases have not been repeated on a large scale.
- A few other clinical trials have resulted in partial recovery (e.g. Stemcell Inc Pathway study in 2015, showing in partial recovery of hand functions in various but not all participants). Study was discontinued





# Recovery level after cell transplant in ‘unproven’ therapies

- Outcome is mostly unknown for it is not measured nor reported
- Anecdotal reports often relate improvement in quality of life, e.g improvement in ability to sweat, for people with a high injury, or “feeling better”/ having lower spasticity...
- Following people going for “stemcell tourism” e.g. on social media, you generally see the following phases:
  - announcement (and often fundraising to pay for the therapy)
  - excitement as the trip to treatment location is nearing
  - reporting most details about the trip and the location
  - reporting about the therapy and possible slight side effects
  - mostly silence about the effects, except for some vague indication (feeling better, etc)
  - going for another round of treatment (as advised by the clinic)

# Is there another way (1)?

## For experimental & innovative therapies:

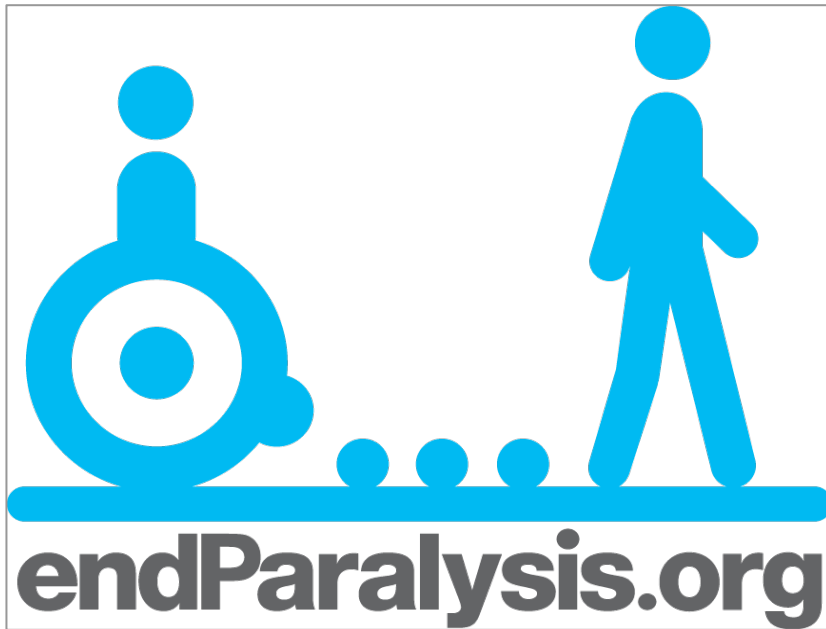
(e.g. stem-cells, pharmaceutical molecules, peptides, enzymes, growth-factors, gene-therapy, biomaterials), with a health risk:

## ACCELERATE THE PATH TO HUMAN TRIALS THROUGH:

- SCI community advocacy
- SCI community pro-actively investing in given promising line of research and bringing it to human trials

KEEP  
CALM  
AND  
DO  
SCIENCE

# Contribute to a future cure!



At the endParalysis foundation, we believe in scientific research and we believe in a cure.

We support targeted research projects that have a chance to be applied to human patients with a chronic spinal cord injury

**WORK WITH US! SUPPORT US!**

[www.endparalysis.org](http://www.endparalysis.org)

# Is there another way (2)?

For therapies with a lot of therapeutic experience and limited therapeutic risk (e.g. e-stimulation/ neuro-stimulation, based on long existing e-stimulator):

**FAST-TRACK/ DISSEMINATE THE TREATMENT IN REAL LIFE:** →ask your neurosurgeon what effects YOU can expect from the therapy (Beware it is NOT a cure, by far, but it might bring you appreciated quality of life). Remark: Some neurosurgeons / clinical researchers are now implanting e-stimulator in patients as pain-relief devices, with insurance coverage, as a neuro-prosthetic/ for neuro stimulation to enhance sensation or movements..

**JUST DO IT.**

**Always** check whether there is a **free**  
clinical trial for you

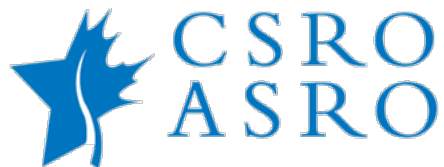


**Spinal Cord Injury Trials**

Connecting Scientists & the SCI community

Go to <http://www.scitrials.org/> to find a  
clinical trial that fits your SCI and needs.

# SCITRIALS.ORG is provided by:



# SCITRIALS.ORG is made possible by:



fuelService

- The free & non-profit fuelService app helps physically-challenged drivers find & get assistance refueling their cars.
- Designed and managed by the spinal cord injury community
- Available in: UK- Ireland – NL – Germany – France – Luxembourg – Belgium – USA – Canada
- Download the free app: search “fuelService” in Appstore/ GooglePlay