Perry Cross
Spinal Research
Foundation

To Cure Paralysis For All

Intensive Rehabilitation Trial

Request For Funding Prospectus

Project aim:

To improve the quality of life for people with a chronic spinal cord injury and change the way rehabilitation is administered in Australia.

Prepared by:

Perry Cross
Spinal Research
Foundation

In association with:

Griffith University, QLD

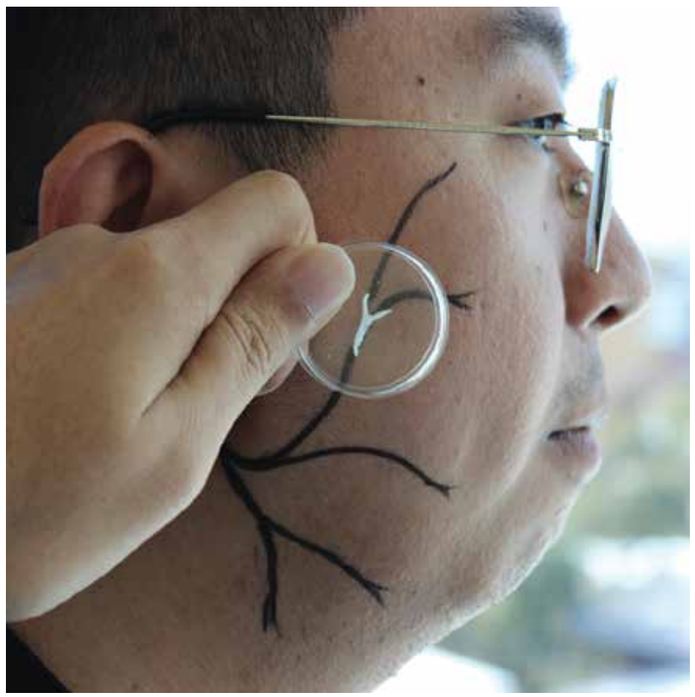
Executive summary

What is the challenge?

A spinal cord injury can happen to anyone at any time. In fact, in Australia, on average one person sustains a spinal cord injury and is paralysed every day[2]. Paralysis is the loss of voluntary movement and often results in being confined to a wheelchair as well as the loss of function and feeling.

$2 billion cost to society

Without an effective cure, the emotional and financial costs to individuals, their families and to our community as a result of a spinal cord injury are life-long. Aside from the devastating personal trauma, the cost to our society to care for people living with a spinal cord injury is over $2 billion a year[4]. This is not sustainable and must change.



Is there a cure?

There is no cure for paralysis but with the support of generous donors and funding partners including The Motor Accident Insurance Commission and The Queensland Government, The Perry Cross Spinal Research Foundation has helped to raise over $12million which has been invested into ground-breaking Australian research focused on finding a cure.

We have made great progress with a world first treatment that involves the transplantation of the patient's own olfactory ensheathing cells (OECs) from the nose into the spinal cord to reform connections. This experimental treatment has shown promising functional outcomes.

Our goal is to conduct a Human Clinical Trial using this transplantation treatment to restore movement in people suffering with paralysis. Before we can do this, we need to prepare the body to move again through intensive rehabilitation. Without long-term activity-based rehabilitation, cell transplantation alone will not be successful.

What is the solution?

Our Intensive Rehabilitation Trial is the next step in getting to a Human Clinical Trial and involves activity-based rehabilitation, combined with a range of physical motor and sensory gym-based activities.

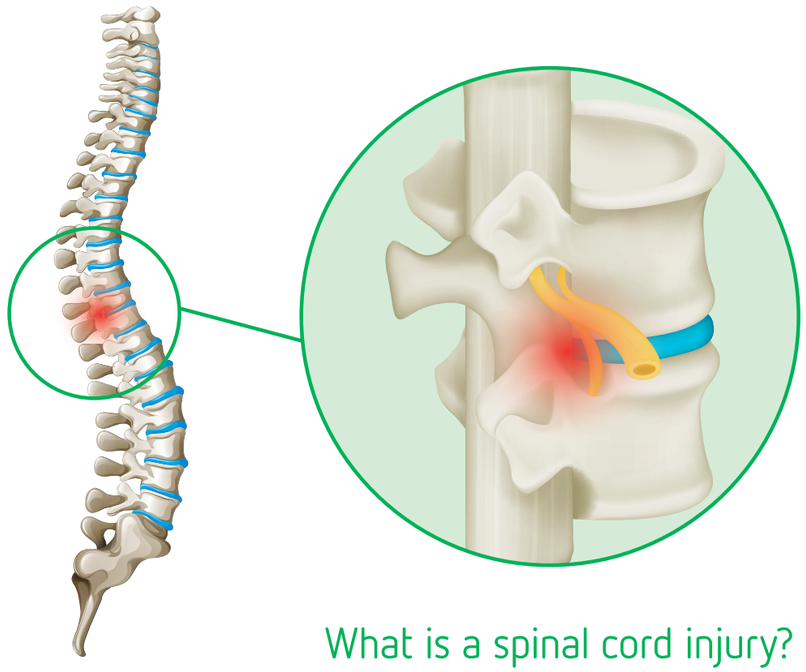
This Trial will examine whether long-term intensive activity-based rehabilitation therapy can be effectively delivered to people living with spinal cord injuries in Australia and whether it improves overall health, social outcomes and functional recovery. This is an important trial that will improve the quality of life for people living with a chronic spinal cord injury and it will also change the way rehabilitation is administered in Australia.

How can you help?

Through generous supporters, like you, funding partners, philanthropists, and our incredible fundraising community, The Perry Cross Spinal Research Foundation has committed $450,125 to begin this trial which will cover the start-up costs as well as funding 5 participants. **We are urgently seeking funding of $916,000 for 10 additional participants to contribute to a robust data set. This is the next critical step in getting to a Human Clinical Trial and finding a cure for paralysis.**

Will you join the movement to get people with paralysis moving again?

What happens if you injure your spinal cord?



What is a spinal cord injury?

The term ‘spinal cord injury’ refers to damage to the spinal cord resulting from trauma (e.g. a car crash) or from disease or degeneration (e.g. cancer). Symptoms may include partial or complete loss of sensory function or motor control of arms, legs and/or body. The most severe spinal cord injury affects the systems that regulate bowel or bladder control, breathing, heart rate and blood pressure.[1]

A spinal cord injury (SCI) can happen to anyone at any time. The injury can result in paralysis and it can mean living the rest of your life in a wheelchair. It is not just about the terrible restriction of being confined to a wheelchair, there is also the loss of independence and freedom and increased isolation. Essentially, having a spinal injury is life altering with huge ramifications as a result.

The spinal cord carries a variety of signals between the brain to the rest of the body. After a spinal cord injury, the motor nerve fibers, which send signals from the brain to the torso and the limbs are impaired and this causes paralysis of the muscles. Destruction of sensory nerve fibers leads to loss of sensations such as touch, pain and the ability to distinguish between hot and cold. A spinal cord injury can also severely limit bladder and bowel control, sexual function, blood pressure and sometimes the ability to breathe unaided.

Apart from living with life-long paralysis, people living with SCI suffer numerous difficulties, with 20-30% [1] showing clinically significant signs of depression, frequent complications including pressure sores, autonomic dysreflexia, and significant decrease in leisure time activities and quality of life.

Aside from the devastating personal trauma, the cost to our society to care for people living with a spinal cord injury is over $2 billion a year.[4]

Without an effective cure, the emotional and financial costs to individuals, their families and to our community are devastating and life-long. We need to find a cure and change this bleak outlook.

Who is at risk?

In Australia, on average, one person sustains a spinal cord injury and is paralysed every day[2] and many of these individuals are young men under the age of 24.

Young people affected by a spinal cord injury have an entire lifetime of very difficult circumstances to deal with.

Ryan Boyd was just 19 years old when a motocross accident left him a quadriplegic. Incredibly, both father and son, John and Ryan Boyd have been unfortunate victims of spinal cord injury after becoming paralysed in motocross accidents. Adding to the heartbreak, Ryan's injury occurred on his dad's birthday.

15,000
Australians have injuries and there are approximately 400 new traumatic spinal cord injuries every year.

Men account for **80%** of spinal cord injuries.

The main cause for injuries

53% vehicle accidents

12% sporting injuries

23% falls

12% other

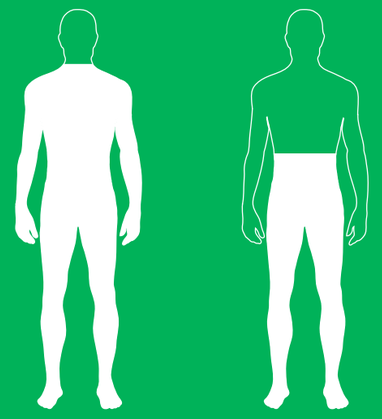
52% of spinal cord injuries resulted in quadriplegia.

48% of spinal cord injuries resulted in paraplegia.

Spinal cord injury at a glance

In Australia, on average, one person sustains a spinal cord injury and is paralysed every day.[2]

Paralysis is the loss or impairment of voluntary movement and the loss of function and feeling.



Quadriplegia **Paraplegia**

over 12 million raised

There are currently 15,000 Australians living with a spinal cord injury. Aside from the devastating personal trauma, the cost to our society to care for people living with a spinal injury is over $2 billion a year.

Since 2010, the Perry Cross Spinal Research Foundation has invested millions of dollars into ground-breaking Australian research focused on finding a cure for paralysis.

Meet Perry Cross AM Cure Crusader

Perry Cross broke his neck in a rugby accident that changed his life forever, 26 years ago.

At the age of 19 Perry was severely injured in a rugby union tackle at Ballymore in Brisbane and told he would never walk again. Paralysed from the neck down, relying on a ventilator to breathe and requiring 24/7 medical care, Perry quickly had to adapt to the profoundly difficult situation.

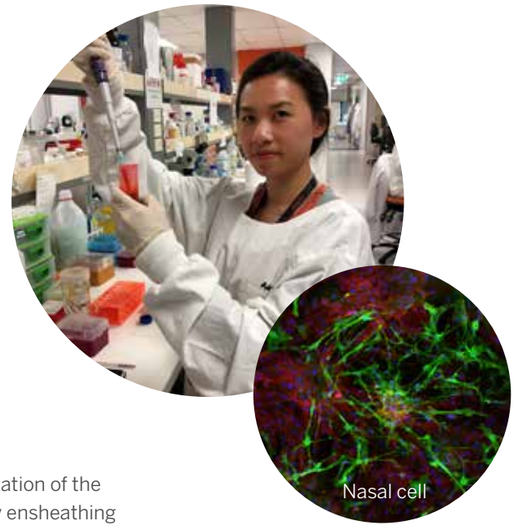
Perry was left a C2 ventilated quadriplegic. Amidst the heart-break, terrible grief and pain, Perry carved out a new lease on life and within a few years, became one of the world's most inspiring motivational speakers and spinal research advocates – with one mission, to find a cure for paralysis. He has since dedicated his life to helping others, raising awareness of spinal injuries and creating a movement that has seen tens of thousands of people applaud, recognise and support the need for urgent spinal cord injury research.

Perry chose to look for the good in life and find a new direction and he has gone on to live an extraordinary life. Inspired by the story of Hollywood actor Christopher Reeve who sustained the same injury, Perry set up the Perry Cross Spinal Research Foundation with the primary aim of finding a cure for paralysis – a mission he's taken on with grace and gusto.

Perry Cross with Christopher Reeve.

Through the support of generous donors and funding partners, The Perry Cross Spinal Research Foundation has helped raise over $12m which has been invested into incredible Australian research focused on finding a cure for paralysis. We have made great progress with a ground-breaking and world first treatment that involves the transplantation of the patient's own olfactory ensheathing cells (OECs) from the nose into the spinal cord to reform connections. This experimental treatment has shown promising functional outcomes. However, we are not there yet and we need funding support to get to our ultimate goal – a Human Clinical Trial.

Is there a cure for paralysis?



Unfortunately not yet, but there is great progress being made in medical research right here in Australia. The Perry Cross Spinal Research Foundation supports and funds The Spinal Injury Project (SIP), which is based at the Menzies Health Institute Queensland (MHIQ) and the Griffith Institute for Drug Discovery (GRIDD) at Griffith University. The Spinal Injury Project is in pursuit of a cure and is working with a laser focus towards the ultimate goal - **a Human Clinical Trial.**

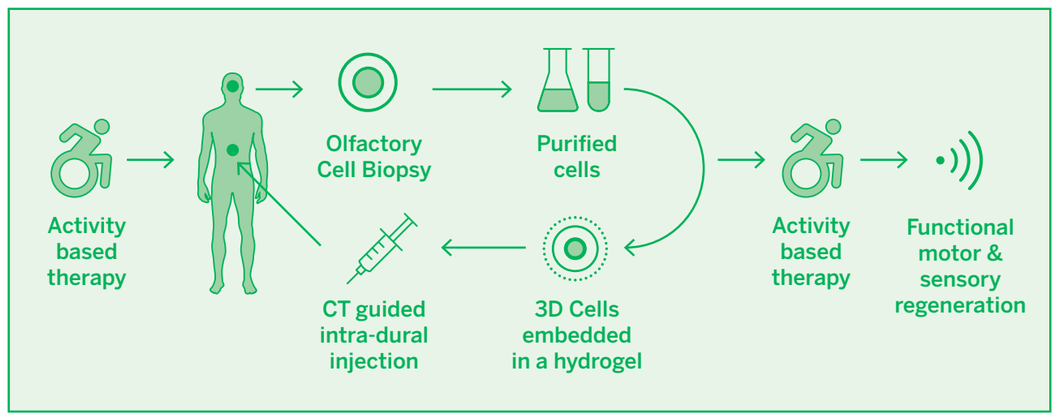
This ground-breaking, world first project was pioneered by 2017 Australian of the Year, Emeritus Professor Alan Mackay-Sim and involves the transplantation of the patient's own olfactory ensheathing cells (OECs) from the nose into the spinal cord. This experimental treatment has shown promise in previous human clinical trials and now needs further refinement.

The SIP team is reinventing and rethinking how cells can grow leading to the creation of new cell products. By combining advanced cell purification techniques and engineering, the team is designing three-dimensional nerve bridges that will help regenerate the spinal cord.

These 3D cell constructs use newly invented, award winning technology involving 3D printed templates. This technology generates 3D nerve bridges that can be used to repair traumatic injuries. This methodology ensures patients receive optimal restoration of motor and sensory function and outcomes are as consistent as possible.

This approach has recently been successfully tested in pre-clinical models and has shown promising functional outcomes. **This incredible approach has the potential to result in the first widely available treatment for spinal cord injury and it is being developed here in Australia!**

This approach consists of several steps; the OEC cells are biopsied, purified, stimulated and then a 3D nerve bridge, made of olfactory cells, will be implanted into patients with chronic spinal cord injury, without the need for invasive surgery.



"Getting told that you will never walk again is not something I want to relive."

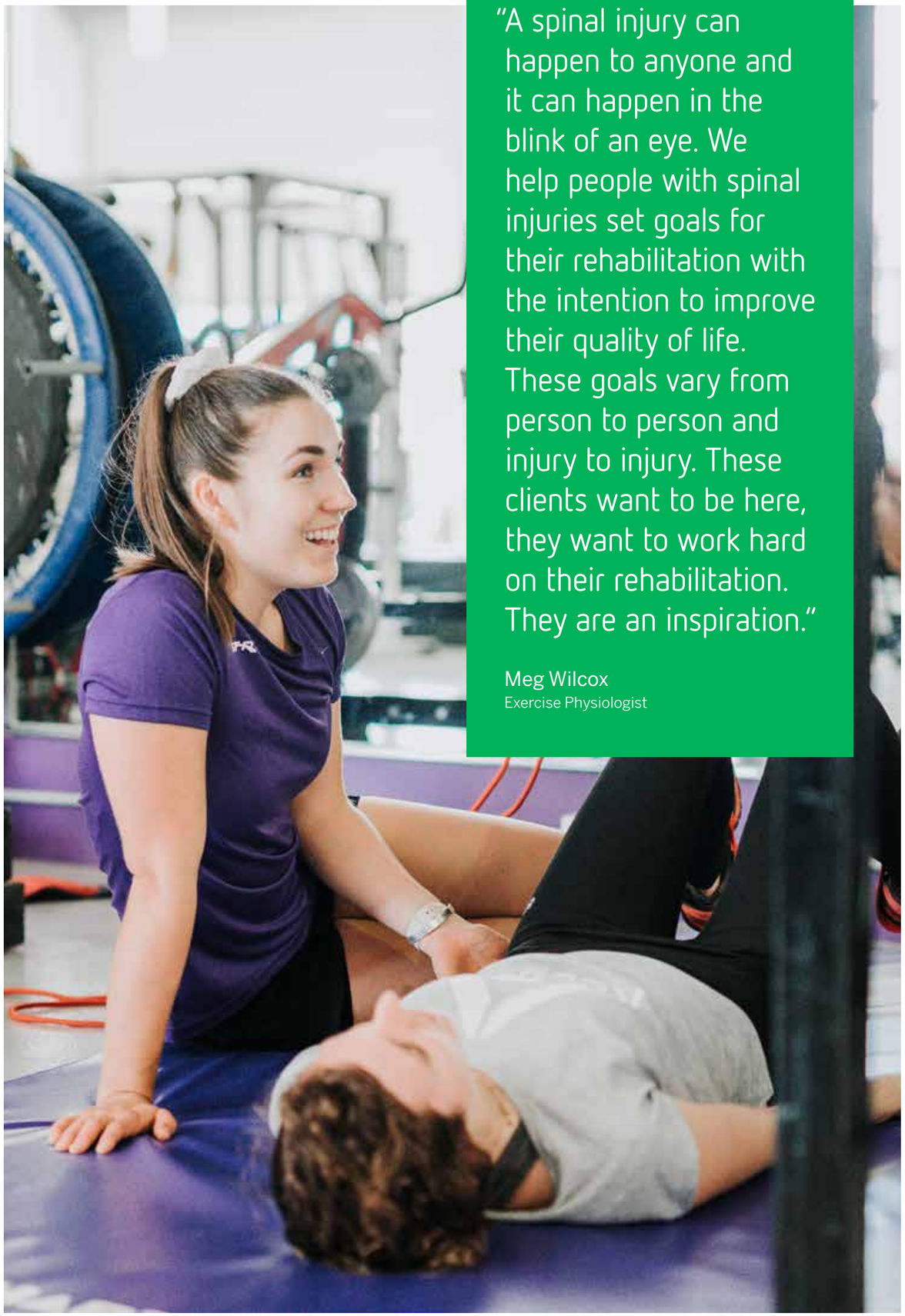
Mick Chisholm

Mick Chisholm is a tough Aussie bloke who loves motocross, is a very hard working business owner and is dedicated to his teenaged kids. His life changed dramatically at age 44 when he had a terrible motocross crash and broke his back (T10, T11 and T12) and became paralysed.

Mick has worked hard to rebuild his life under very difficult circumstances. There has been many ups, downs and losses and he uses rehabilitation and time at the gym to maintain his physical and mental health.

Mick's resilience, work ethic and determination is inspiring. He is hopeful the Perry Cross Spinal Research Foundation's Intensive Rehabilitation Trial will help people regain movement and hopefully walk again.

He dreams of one day being able to step out of his wheelchair and walk his daughter down the aisle on her wedding day.



"A spinal injury can happen to anyone and it can happen in the blink of an eye. We help people with spinal injuries set goals for their rehabilitation with the intention to improve their quality of life. These goals vary from person to person and injury to injury. These clients want to be here, they want to work hard on their rehabilitation. They are an inspiration."

Meg Wilcox
Exercise Physiologist

What is the next step in finding a cure?

Our goal is to conduct a Human Clinical Trial and restore movement in people suffering with paralysis. However, before we can do this, we need to prepare the body to move again through intensive rehabilitation.

Exercise and rehabilitation are the key to helping the spinal nerves to reconnect. Our government recommends 30 minutes of exercise a day for good health and well-being and people with a spinal cord injury are no different. The benefits to movement aren't only physical, there are also great benefits emotionally and socially.

Our Intensive Rehabilitation Trial is the next step in getting to a Human Clinical Trial and involves activity-based rehabilitation, combined with a range of physical motor and sensory gym-based activities. This Trial will examine whether long-term intensive activity-based rehabilitation therapy can be effectively delivered to people living with spinal cord injuries in Australia and whether it improves overall health, social outcomes and functional recovery.

Rehabilitation and activity-based therapy (ABT) through this Trial will prepare the body to move again by allowing the nervous system to make new connections and re-learn the necessary fine control needed for proper motor and sensory function.

Why is exercise and rehabilitation important for someone who is paralysed and cannot move?

Global research shows rehabilitation can have very positive results after a spinal cord injury. Long-term rehabilitation programs can improve health outcomes like joint function and blood flow and as a result can enhance mobility and independence.

Without long-term activity-based rehabilitation, cell transplantation alone will not be successful. This is why this Trial is the next step in finding a cure for paralysis.

Why are Injured Australians being left behind?

Rehabilitation after an injury is common practice across all kinds of injuries and in many countries across the world. It is a concept we are all familiar with – repairing the body after injury. Alarmingly it is not standard practice in Australia to administer rehabilitation and activity-based therapy for someone after they sustain a spinal cord injury. This is incredible isn't it?!

Across the globe rehabilitation after a spinal cord injury is standard practice and the benefits have been proven. In fact, there is strong evidence gathered internationally (Europe, USA and Canada) that demonstrates enhanced recovery and improved quality of life with better health as a result of activity-based therapy after an injury. ABT can also support people living with SCI to become more independent and as a result, enable them to return to work.

So why isn't ABT available to Australians?

Unfortunately, Australians living with chronic spinal cord injury have extremely limited access to intensive rehabilitation and ABT as it is not part of standard care practice after discharge from acute primary care. In Australia, individuals covered by the NDIS can apply on a case-by-case basis for ABT. Yet access is varied, limited and not standardised. For those not covered by the NDIS, ABT can become too expensive, thereby limiting their treatment options.

Our vision is that this Intensive Rehabilitation Trial will identify enablers and barriers that contribute to participation in intensive, long-term, personalised ABT. Ultimately, we hope ABT will become a clinical care standard in Australia, leading to enhanced outcomes for individuals with a dramatic increase in socioeconomic benefits for our community.

Curing paralysis will literally benefit all Australians by saving the economy millions of dollars a year. It should therefore be a priority for the Australian government, communities and individuals to fund this medical research. We need your help to raise the funds to run this Trial and find a cure.

What are the overwhelming economic benefits to finding a cure?

The reality is, spinal injuries cost individuals, families and the economy billions of dollars every year. That is an unbelievable amount of money! These people want to move again, they want to be independent, join the workforce and contribute to the economy. They most certainly do not want to be a burden.

In 2020, the socioeconomic impact of spinal cord injury (SCI) in Australia is overwhelming. A 2009 Access Economics report estimated the annual cost to our society to care for people with a spinal cord injury is $2 billion per annum. In 2020, with an estimated 15,000 people living with SCI, the economic burden will be alarmingly higher.

Based on these figures, if our Intensive Rehabilitation Trial can improve patient outcomes by 20% for 20% of the population living with spinal cord injury, we can save at least $800 million per decade for the Australian economy. These numbers are overwhelming – it is urgent we address barriers that prevent people living with SCI from recovering to their full potential after injury and create a national approach to long-term rehabilitation.

What are some of the typical costs for someone with a spinal injury?

- Hospital fees.
- Carers costs including, in some cases, 24/7 care charged at an hourly rate.
- Equipment costs including consumables, a ventilator, wheelchair, adjusted vehicle, voice assisted technology in the home.
- Allied health support fees including rehabilitation and occupational therapy.

"We know rehabilitation can prepare the body to move again and so we need to change how rehabilitation is administered in Australia to improve the quality of life for people with a spinal cord injury."

Perry Cross AM
Founder & Executive President
Perry Cross Spinal Research Foundation

How will the Intensive Rehabilitation Trial work?

This Trial will be the first of its kind in Australia as it will measure multiple outcomes that are directly aligned with the National Disability Strategy 2010-2020.

This is important because the National Disability Strategy 2010-2020 identifies that we need to remove barriers that prevent people with disability living fulfilling lives and to provide services that enable people to regain health and independence. Our Trial embodies this important goal – we are focused on improving the quality of life for people living with a spinal cord injury.

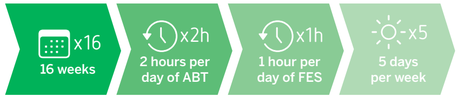
An intensive, long-term rehabilitation program that improves health outcomes, enhances mobility and independence, and enables people to return to work would directly address these priority areas of the National Disability Strategy.

What are the goals of this Trial - what are we trying to achieve?

- Improve the overall health and wellbeing for individuals.
- Increase mobility for people suffering paralysis.
- Improve social and psychological outcomes for individuals.
- Prove rehabilitation should be standard practice after a spinal cord injury for Australians.
- Change how rehabilitation after an injury is administered in Australia.
- Prepare the body to move again.
- Get to a Human Clinical Trial!

Trial outline

The trial will combine personalised activity-based motor and sensory therapy, functional electrical stimulation (FES) and gait training during an intensive period of;



After this period, participants will then return home and continue a prescribed personalised program of activities. Participants will be supported by online consultations with the service providers, health professionals, and peer groups, and by a specialised app (Spinal Injury Project Rehabilitation app).

Throughout the trial, functional, medical and psychosocial assessments will be conducted to determine participants' outcomes.

For maximum results, the goal is to see 15 participants included in this Intensive Rehabilitation Trial.

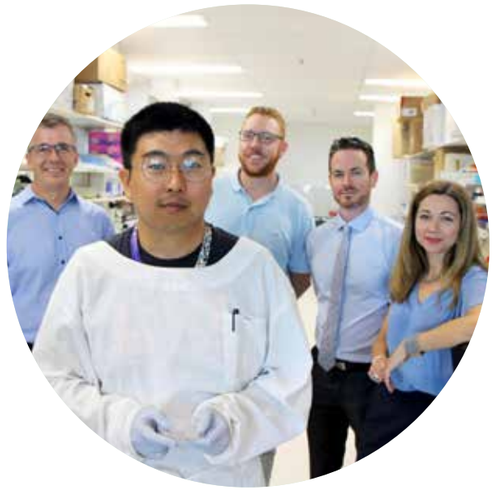
Intensive Rehabilitation Trial

There will be 15 participants in this Intensive Rehabilitation Trial.

Participants will train intensively at the gym for 16 weeks and will then return home to continue their training.

Participants will be supported online with a specialised app.

How can you help?



You have the opportunity to invest in medical history by improving the quality of life for people with a chronic spinal cord injury and changing the way rehabilitation is administered in Australia.

Through the generous donations of funding partners, philanthropists and our incredible fundraising community we have already committed $450,125 to begin this trial. This will cover the start-up costs as well as funding 5 participants to complete the rehabilitation as outlined. This trial of 5 participants is set to commence at the beginning of 2021.

To complete the trial we are looking for an additional $916k to fund an additional 10 participants.

We are seeking $916,000 in funding for 10 additional participants to contribute to a robust data set as outlined here;

Start Up Costs $137,000 – Funded	**Trial Group 1 $313,000 – Funded**	**Trial Group 2 $458,000 – Not yet funded** (investment required)	**Trial Group 3 $458,000 – Not yet funded** (investment required)	**Human Clinical Trial $30M – Not yet funded** (investment required)
• Contract Research Organisation (CRO) scope • Approvals • Database set up • Protocol development	• 5 participants from the local south-east Queensland / Northern NSW region	• 3 participants from the local south-east Queensland / Northern NSW region and 3 participants from around Australia • Data management / biostatistics • Management by CRO	• 3 participants from the local south-east Queensland / Northern NSW region and 3 participants from around Australia • Management by CRO	• Our ultimate goal is to develop a therapy for SCI and cure paralysis.
In progress		**Urgently needed**		**Ultimate goal**

How will your investment have an impact?

Investment Value	Impact	Number of Gifts Required
$150,000	Fund a dedicated Research Fellow to drive the clinical trial and report the results	1
$91,000	Support one person living with paralysis to take part in the trial	3
$38,000	Fund 160 hours of rehabilitation, medical evaluations and physiotherapy for one person living with paralysis to take part in the trial	5
$23,000	Fund the accommodation for a non-local participant for 16 weeks whilst they participate in the trial	6
$10,000	Fund 70 hours of rehabilitation (exercise physiology) for one person living with paralysis	8
$5,000	Fund the transportation to the Gold Coast and the transport to the Rehabilitation centre (Making Strides) for a participant living with a spinal cord injury and their carer	8
$2,000	Fund 14 hours of rehabilitation (exercise physiology) for one person living with paralysis	8
$1,600	Fund home equipment for one participant to complete the trial in the at-home phase	10
$1,200	Fund 8 Neurological and Psychological Evaluations for one person living with paralysis partaking in the trial	11
$916,000	Total Cost for 10 participants in the Intensive Rehabilitation Trial	
$30M	Estimated cost of a Human Clinical Trial	

Will you join the movement to get people with paralysis moving again?

The Perry Cross Spinal Research Foundation values all contributions. We would love to discuss how you can make an impact.

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References
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Making Strides Rehabilitation

I want to be selected for the Trial; how do I get involved?

The good news is 15 participants are needed to achieve robust results. The bad news is not everyone who wants to be involved will be able to be selected.

Ten participants will be recruited by an independent body from the local south-east Queensland/Northern NSW region (within reasonable daily traveling distance to the service provider) and five participants will be recruited from around Australia (accommodation will be provided). It is necessary to include both local participants and Australia-wide participants as it is critical that the Trial is accessible to all Australians.

Participants will be people living with SCI aged 18–65 years who have had traumatic SCI and have gone through primary rehabilitation, with stable neurological level and functional ability of more than six months in duration. There will be 7–8 participants with paraplegia and 7–8 participants with quadriplegia with complete and sensory incomplete injuries.

Exclusion criteria are those that limit people's ability to participate or pose health risks, including, but not limited to, significant concomitant central nervous system or other disorders that limit ability to exercise; active medical or psychiatric illnesses, uncontrolled and excessive pain, symptomatic or radiologically demonstrated ischaemic heart disease, chronic obstructive pulmonary disease, contraindications for FES, currently participating in other trials (medical or therapeutic interventions).

Although not everyone who wants a place in the Trial will be able to be selected, the goal is to use the research results to get to a Human Clinical Trial and ultimately cure paralysis for all.

How do I get selected for the Trial?

Unfortunately, there are a limited number of participants in the Trial and these people will be chosen by an independent body based on a strict selection and exclusion criteria.

Who are the incredible people striving to make medical history?

We have assembled an experienced and diverse team of chief investigators, associate investigators and external partners to deliver, manage and report on the Trial.

Meet the A team:

CIs AProf James St John and AProf Jenny Ekberg lead the major spinal cord injury cell transplantation therapy project. Together they lead a large team and have a comprehensive understanding of the needs of the clinical trial management. They will direct the project, coordinate the analyses and write the manuscripts for publication.

CI Dr Marie-Laure Vial is a research fellow within the Clem Jones Centre with a focus on innovative translational research outcomes. She has a comprehensive knowledge of the design and implementation processes to take products along the pipeline to market delivery. She will work with the various partners to facilitate product identification and promotion of outcomes to stakeholders.

CI Prof Michel Coppieters is an experienced physiotherapist academic who specialises in pain and musculoskeletal recovery, including spinal cord injury. He will provide oversight of the clinical trial management and interpretation of the results, particularly with regards to pain outcomes.

CI Ms Emma Warner is a clinical neurophysiotherapist and academic who has international clinical experience working with people undergoing long-term intensive rehabilitation including spinal cord injury. She will oversee the physiotherapy design of the cSCI-ABT and will provide input into the appropriate modifications to the rehabilitation program if required. She will provide interpretation of the results.

CI Dr Dinesh Palipana is a medical clinician who also lives with spinal cord injury (quadriplegia). His medical knowledge together with his lived experience offer exceptional insight into the journey of recovery from a medical, psychological and community viewpoint. Dinesh will interpret the medical, functional and psychosocial assessment data, particularly with his viewpoint of lived experience.

CI AProf Dianne Shanley is a clinical psychologist and academic who leads the Griffith University Allied Health and Psychology Clinics. She has extensive experience with conducting appropriate surveys and assessments to determine the positive and negative experiences of clients. She will conduct and analyse the psychosocial assessments of participants during the trial.

CI Rayfield is a research fellow within the Clem Jones Centre with a focus on clinical trial delivery. He has training in clinical trial management and will work with the CRO to ensure timely and appropriate delivery of the project and outcome reporting.

CI Dr Matthew Barton is a registered nurse and an experienced researcher in nerve regeneration with numerous clinical collaborations and is an outstanding teacher and communicator. He will develop, manage and interpret the survey data in conjunction with CI Shanley.

CI Dr Michael Todorovic is an outstanding science communicator and academic. He will develop and manage the survey data in conjunction with CIs Shanley and Barton.

The associate investigators AIs Ms Genny Kroll-Rosen and Mr Jim Barrett are two of the Managers and Directors of the specialist rehabilitation service provider Making Strides. They have co-designed and alpha/beta tested the SIPR app and co-designed the cSCI-ABT program; Making Strides staff will deliver the on-site program and will provide the ongoing remote support for the at-home program.

The research fellow will coordinate the program, liaise with the CRO and the rehabilitation provider, manage the data storage, perform the primary analyses of the medical and functional assessment data and draft the reports and publications.

Notes

Thank you to NOVA Press for printing this publication.

This incredible image is a heart-shaped 3D cell culture made up of olfactory ensheathing cells.

Perry Cross Spinal Research Foundation

To Cure Paralysis For All