

2023 Recruitment Campaign - Q&As

What is Project Spark?

Project Spark is a 5-year program of clinical trials and community-based studies across Australia. Starting in 2021, the objective is to test, validate and develop neurostimulation treatments for people with a spinal cord injury.

What is neurostimulation?

Neurostimulation is a potentially revolutionary treatment for people with spinal cord injuries. It uses electrical currents to wake up the spinal cord, reconnecting the brain and body, and to date has seen some unbelievable results.

How is neurostimulation applied?

Project Spark focusses on non-invasive neurostimulation, using electrodes placed onto the skin. It is inexpensive, safe and very easy to make available to all those who could benefit after the trials have finished.

What's so promising about neurostimulation?

In small studies overseas, the results have been nothing less than unbelievable. We have seen people stand and walk. We have seen improved hand control. We have seen the return of lost vital functions such as bladder and bowel control, and cardiovascular stability.

Neurostimulation is unique. No other experimental therapy has seen an equivalent level of meaningful return of feeling and function in trial participants, and no other has the potential to be ready for mainstream distribution in the short term.

What clinical trials currently exist under Project Spark?

1. **The eWalk trial:** Australia's first neurostimulation clinical trial, aiming to restore the walking ability for incomplete paraplegics, recruiting in Sydney, Melbourne and three international sites.
2. **Get a Grip:** The second neurostimulation trial aims to improve hand, arm and respiratory function for people with quadriplegia. This study is taking place at Sydney's Clyde and St Peter's NeuroMoves clinics and the first of up to 96 volunteers will commence treatment in May 2023. A Perth site is due to follow shortly after.
3. **eWalk 2.0,** An expanded phase 3 trial treating 142 incomplete

- quadriplegics and paraplegics across the country. Commencing 2024.
4. **Combination Therapy.** A fourth study exploring a combination of therapies to improve the arm, hand and respiratory function in people with quadriplegia. Commencing 2024.

How does the Get a Grip study work?

This trial is being conducted in the community, which means it is more accessible for people to come and participate. It's still a research trial, but rather than being something that might be a placebo controlled trial, where some people get the real stimulation and some people don't, everybody gets the real stimulation in this trial. It's a trial that's open to everybody with a cervical spinal cord injury, as long as they are able to have neurostimulation.

Why should I take part in a clinical trial?

Neurostimulation has the potential to improve life-changing function. Such a simple intervention could really impact someone's life, to mean that they can pick up an object, have better balance, be able to breathe better; there really are quite endless possibilities to the positive effect neurostimulation can have.

What's involved with being on a clinical trial?

Each clinical trial will have different criteria and conditions associated with being a participant.

For example, the Get a Grip study will mean attending a NeuroMoves centre three times a week, for a six week period, where stimulation would be applied for a half hour treatment session.

Is there any surgery involved in your trials, will it be painful?

Every trial within Project Spark focuses on non-invasive neurostimulation, using electrodes applied on to the skin. The majority of people will find this painless, some people may feel some discomfort but the stimulation is trialled and tailored prior to ensure that it is suitable for each person.

Can I volunteer for more than one trial?

Yes, absolutely - subject to meeting the eligibility criteria. Some trials do not allow enrollment in another until the first is finished.

What should I do if I want to be on a trial?

It's really important to register your interest as soon as possible if you want to be part of these groundbreaking trials. Spaces are limited, so we can't guarantee a spot. Visit our clinical trials page, where more information on how to register for current trials can be found, click [here](#).

What if I struggle to get to the clinical trial site location?

Some trials may provide travel assistance and cover some expenses - check the trial participant information sheet for details.

What if I know someone that could benefit from the trial?

Project Spark really could change the life of a friend, or a colleague, or a family member. So please encourage them to get in contact – we'd love to hear from them.

What if I don't meet the eligibility requirements for current trials?

The majority of our trials are based with our partners at Neuroscience Research Australia (NeuRA) – we'd encourage you to register your details with their SCI volunteer database [here](#), so they have a record and are able to contact you for any future studies. Some research only requires a one off visit, or through remote access or you may be able to participate in vital information gathering via a survey.

Why is SpinalCure continuing to fund neurostimulation clinical trials?

Nobody has yet done the rigorous gold-standard clinical trials required to give unequivocal scientific validation of transcutaneous stimulation (neurostimulation). Our eWalk trial is the first in the world to do this.

The second of our trials – the Get a Grip Trial – is actually testing two different types of stimulation, and with both complete and incomplete quadriplegics.

The third trial (funded by an MRFF grant) is our first to test a combination therapy in the hope of an even more effective treatment. It will be comparing the benefits of neurostimulation alone, acute intermittent hypoxia (another therapeutic option) alone, and with a combination of the two.

We are on the verge of being able to make the unbelievable, believable hence we're doubling down on our push to fund these trials and change lives.