PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Transcutaneous spinal cord stimulation combined with locomotor training to improve walking ability in people with chronic spinal cord injury (eWALK2.0)

Professor Jane Butler

1. What is the research study about?

You are invited to take part in a research study. The study wants to understand the effects of a new training program on the walking ability of people with a spinal cord injury. This training program consists of 12 weeks of electrical stimulation applied to the skin over the spinal cord, combined with walking and exercises.

2. Who is conducting this research?

The study is being carried out by the following researchers:

Role	Name	Organisation
Principal Investigator	Prof Jane Butler	NeuRA
Co-Investigators	Prof Simon Gandevia	NeuRA
	Dr Claire Boswell-Ruys	NeuRA, UNSW
	Dr Elizabeth Bye	NeuRA, Prince of Wales Hospital
	Dr Terry Trinh	NeuRA, UNSW
	Prof Gavin Williams	Swinburne University of Technology
	Ms Zoë Djajadikarta	NeuRA
	Ms Nadine Fuchs	NeuRA

Research Funder: This research is funded by a Medical Research Future Fund grant.

3. Inclusion/Exclusion Criteria

You can take part in the study if you have a cervical or thoracic spinal cord injury and meet **all** of the study's inclusion criteria and **none** of the study's exclusion criteria. The list of criteria is extensive to ensure the study is conducted in a safe manner i.e. participants have no contraindications to the stimulation or locomotor training. After an extensive screening process, you may not be eligible for the study.

Inclusion Criteria

- Aged 16 years or older at the time of consent and able to give informed consent;
- Diagnosed with a spinal cord injury between the levels of C2 and T11 at least one year ago;
- Willing and able to participate in a training program three times a week, for 12 weeks;
- Able to take at least two steps with no harnessed body weight support. The steps may be completed with assistance (physically swinging the leg through by the therapist is not allowed), braces, gait aids or within parallel bars;
- Have reflex responses in at least one anterior thigh muscle when stimulated with spinal stimulation
- Have a minimal amount of voluntarily activity in one or more leg muscles. This means a lower limb motor score of at least 4/50 on the International Standards for Neurological Classification of Spinal Cord Injury;
- Willing and able to participate in the training program three times a week for 12 weeks, and a follow-up telephone call approximately 6 months later;

Neuroscience Research Australia ABN 94 050 110 346
Margarete Ainsworth Building
139 Barker Street (PO Box 1165)
Randwick Sydney NSW 2031 Australia
T +61 2 9399 1000 F +61 2 9399 1005
neura.edu.au

- Considered by their spinal specialist to be medically stable and able to take part in the training program.

Exclusion Criteria

- Have a history of clinically significant autonomic dysreflexia in response to electrical stimulation;
- Cannot tolerate spinal stimulation at 50% of the intensity required to evoke reflexes in your leg muscles;
- Have a history of hypotension in response to prolonged standing;
- Have a progressive neurological disease or other major neurological condition other than the spinal cord injury (e.g., severe traumatic brain injury or stroke);
- Have a history of multiple broken bones in the legs, family history of a person whose bones break easily or any disorders of the bone (e.g. Paget's disease);
- Had surgery in the last 3 months. You may still be eligible if you had minimally invasive surgery (e.g. keyhole procedure). This must be determined by your spinal specialist or GP;
- Have a progressive syringomyelia (syrinx; fluid-filled cyst or cavity in spinal cord) on recent MRI. You may still be eligible if your syringomyelia is non-progressive. This must be determined by a neurosurgeon;
- Have severe lower limb spasticity or contractures;
- Have a serious medical condition preventing you from adhering to the protocol. Examples include cognitive impairment (i.e. trouble remembering or learning), drug dependency, psychiatric illness or behavioural problem;
- Have a moderate to severe pressure ulcer (Stage 3 or 4);
- Have a muscle-skin graft that was taken from a locomotor muscle such as the gluteal or hamstring muscles;
- Have a cardiac pacemaker, a lower limb or vertebral fracture, a baclofen pump, an electronic implant or are pregnant;
- Have an upper limb injury that prevents you from being able to hold yourself up with your arms;
- Have a history of stem cell or olfactory ensheathing cell therapy in the last 5 years;
- Are taking part in another clinical trial, including the follow-up period.

4. Do I have to take part in this research study?

Participation in this research study is voluntary. If you do not want to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any time. Your decision will not affect your relationship with the University of New South Wales or Neuroscience Research Australia.

5. What does participation in this research require?

If you decide to take part in the research study, you will be asked to sign and return this Participant Information Statement and Consent Form. First, you will take part in a screening assessment to check you meet all the criteria. This may include trialling the stimulation to see if your body responds and tolerates it.

Neuroscience Research Australia ABN 94 050 110 346
Margarete Ainsworth Building
139 Barker Street (PO Box 1165)
Randwick Sydney NSW 2031 Australia
T +61 2 9399 1000 F +61 2 9399 1005
neura.edu.au

You will take part in 3 assessment sessions at NeuRA or a NeuroMoves gym. Two will be prior to the 12-week training program, the other will be immediately after the 12-week training program. You will also receive a follow-up phone call approximately 3 months after the 12-week training program. We will ask you a few questions about your walking ability, pain, spasticity and quality of life.

This training can take place at Neuroscience Research Australia (NeuRA) in Randwick or at one of the designated NeuroMoves gyms around Australia.

You may also be contacted and invited to participate in a qualitative interview at the end of the 12-week training period. The interview will allow you to share your experiences of participating in the trial. The interview is optional.

Training Sessions
You will be randomly selected to receive either spinal stimulation or a placebo during your training sessions. The placebo is something that looks and feels like spinal stimulation but that we know will not have any treatment effect (termed a placebo). You and the therapists who provide the training will not know which group you are in.

During the training sessions, you will practice walking on a treadmill and overground. Depending on your walking ability, you may use braces, a walking frame, a safety harness or parallel bars when walking overground. A maximum of 60 minutes will be allocated for your training session. The goal for each session is to walk for 30 minutes. You will be able to have regular rests as required. One experienced physiotherapist or exercise physiologist with up to two assistants will conduct your training session. They will assist you as required.

With your consent, we will film some of your training sessions. If you do not agree to be filmed, you can still take part in the study.

All session times can be flexible and arranged between yourself and the research team.

Assessment Sessions
You will undergo clinical tests that assess your walking ability, lower limb strength, lower limb spasticity and lower limb reflexes. You will complete questionnaires that assess your independence, neuropathic pain and quality of life. You will also be asked to set a goal at the beginning of the 12-week program and rate your ability to perform that goal at the end of the program. You will also be asked to provide a saliva sample to test for genes thought to influence neuroplasticity.

Walking assessments
You will be asked to walk as far as you can within a 2-minute period. You will be able to use braces, gait aids, parallel bars and assistance (physically swinging the leg through by the therapist is not allowed) if required. You will also be asked to complete a questionnaire about your walking ability.

Strength and sensation assessment
We will use a standardised assessment tool consisting of lower extremity muscle strength and sensation. This will include a test of your anal muscle strength and sensation. From this assessment we will be able to classify your injury severity.

Neuroscience Research Australia ABN 94 050 110 346
Margarete Ainsworth Building
139 Barker Street (PO Box 1165)
Randwick Sydney NSW 2031 Australia
T +61 2 9399 1000 F +61 2 9399 1005
neura.edu.au

Spasticity
Your lower limbs will be passively moved as you lay on a rehabilitation bed. We will also ask you about the impact of your spasticity on your daily life.

Quality of life
You will be asked to complete a short questionnaire consisting of five questions. These questions ask you to rank your health state in five domains: mobility, self-care, usual activities, pain and anxiety/depression. We will also ask you to rate your overall health using a simple scale.

Neuropathic pain
You will be asked to rate your neuropathic pain over the past week using a simple scale.

Saliva sample for genetic testing
You will be asked to wipe an oral swab on the inside of your cheek.

This test is optional. You can still take part in the study if you do not wish to provide a saliva sample for genetic testing.

We will only use your saliva sample to test for genes thought to influence neuroplasticity. Neuroplasticity can be thought of as the ability of your brain and spinal cord to change in response to a treatment. The samples will not give you any information about your health.

6. Are there any risks to taking part?

Walking assessment and training
You may become unstable or stumble. The safety harness and therapists will ensure you do not fall to the ground.

You may become physically tired. You can take as many breaks as you like during the training.

You may experience muscle soreness 1-2 days after the training session, as is common following exercise.

Electrical stimulation
Electrical stimulation can cause skin burns if the electrodes are not properly secured or there is a small cut or abrasion under the electrodes. To avoid skin burns, we will inspect your skin prior to applying the electrodes. We will also check that the electrodes are firmly attached throughout the training session. We will stop testing if you report any pain, or if any redness is observed on the skin around the electrode. In the rare case of a burn, you will be offered first aid care.

In rare cases, the adhesive used to apply surface electrodes can irritate the skin. We will ask you about skin allergies prior to applying the electrodes. You will be offered first aid if you have a skin reaction.

Neuroscience Research Australia ABN 94 050 110 346
Margarete Ainsworth Building
139 Barker Street (PO Box 1165)
Randwick Sydney NSW 2031 Australia
T +61 2 9399 1000 F +61 2 9399 1005
neura.edu.au

There is a small risk that the electrical stimulation triggers autonomic dysreflexia. This is a form of hypertension that can occur in people with a spinal cord injury. Because you will have met the study's inclusion and exclusion criteria, the risk of electrical stimulation triggering autonomic dysreflexia is low. All investigators will be trained in how to respond to autonomic dysreflexia.

Bowel or bladder incontinence
There as a ~1% chance of a bladder or bowel accident. This is due to the stimulation of the spinal cord and associated nerves that supply the bladder and bowel. To reduce the chances of this happening, we will ask you to empty your bladder and bowel before and after each training session and assessment. If incontinence occurs, the gym/research facility has adequate resources (accessible shower and change room) to assist.

7. Reimbursement
We are unable to reimburse you for your time in this study. Travel reimbursement will be provided for all participants to attend assessments, locomotor training sessions and other trial related aspects, while travel funding lasts. Where reasonable we will seek to reimburse or fund your travel, however it is unlikely that the trial will be able to fund air travel or hotel accommodation.

8. What are the possible benefits to participation?
This study aims to further medical knowledge, and may improve future treatment of people with a spinal cord injury. There is no evidence yet, that electrical stimulation of the spinal cord improves function and walking ability. Therefore, participation in this trial (regardless of your group allocation) may or may not benefit you. You will only have access to this treatment, if you are participating in the trial an only for the duration of the program.

9. What will happen to information about me?
By signing this document, the Participant Information Statement and Consent Form, you consent to the research team collecting and using information about you for the research study. We will store your information for at least 15 years after we have published the first scientific paper about this study. Your information will be stored in a non-identifiable way at NeuRA. Your information will only be used for the purpose of this research study.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by NeuRA. You have the right to request correction and amendment of this information. You have the right to make a complaint about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how NeuRA protects personal information is available in the NeuRA Privacy Policy, available at www.neura.edu.au/privacy.

10. How and when will I find out what the results of the research study are?
The research team will report the results of this study in a variety of ways: in scientific papers, at scientific and clinical meetings, and on our website and social media. All reports will be done in a way that will not identify you.

Neuroscience Research Australia ABN 94 050 110 346
Margarete Ainsworth Building
139 Barker Street (PO Box 1165)
Randwick Sydney NSW 2031 Australia
T +61 2 9399 1000 F +61 2 9399 1005
neura.edu.au

If you would like to receive a copy of the results, you can include your contact details in the space provided below on this Participant Information Statement and Consent Form.

11. What if I want to withdraw from the research study?

You can withdraw from the study at any time without having to give a reason. This can be done by completing the Withdrawal Form located at the end of this Participant Information Statement and Consent Form. The Withdrawal Form allows you to select whether you would still like to take part in the assessment sessions, and what should be done with your information collected so far.

12. What should I do if I have further questions about my involvement in the research study?

If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following members of the research team:

Research Team Contact Details

Name	Prof Jane Butler	Prof Simon Gandevia
Position	Senior Principal Research Scientist	Senior Principal Research Scientist
Telephone	9399 1608 / 0438677267	9399 1617 / 0405141489
Email	j.butler@neura.edu.au	s.gandevia@neura.edu.au

If you experience distress at any point please talk to the research team, or contact support services like Beyond Blue:
Beyond Blue contact number: 1300 22 4636
https://www.beyondblue.org.au/

What if I have a complaint or any concerns about the research study?

If you have a question or complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

Complaints Contact

Position	UNSW Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	

Neuroscience Research Australia ABN 94 050 110 346
Margarete Ainsworth Building
139 Barker Street (PO Box 1165)
Randwick Sydney NSW 2031 Australia
T +61 2 9399 1000 F +61 2 9399 1005
neura.edu.au

Consent Form – Participant providing own consent

Declaration by the participant

- ☐ I understand I am being asked to provide consent to participate in this research study;
- ☐ I have read the Participant Information Sheet or someone has read it to me in a language that I understand;
- ☐ I understand the purposes, study tasks and risks of the research described in the study;
- ☐ I provide my consent for the information collected about me to be used for the purpose of this research study only (unless indicated otherwise on page 4, point 9).
- ☐ I have had an opportunity to ask questions and I am satisfied with the answers I have received;
- ☐ I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
- ☐ I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only;

  Name: _____

  Address: _____

  Email Address: _____

- ☐ I understand that I will be given a signed copy of this document to keep;

Contacting my local doctor and/or specialists

- ☐ I give my permission for the study staff to contact my local doctor and/or specialist to obtain any missing information about my spinal cord injury.

Consent to saliva sample for genetic testing
This test is optional. If you do not wish to provide a saliva sample for genetic testing, you may still participate in the study. Please check the appropriate box:

- ☐ I consent to have my saliva collected and analysed.
  Or
- ☐ I do not consent to have my saliva collected and analysed.

  ☐ Please tick this box if you would like to know your variant of the BDNF gene

Neuroscience Research Australia ABN 94 050 110 346
Margarete Ainsworth Building
139 Barker Street (PO Box 1165)
Randwick Sydney NSW 2031 Australia
T +61 2 9399 1000 F +61 2 9399 1005
neura.edu.au

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Transcutaneous spinal cord stimulation combined with locomotor training to improve walking ability in people with chronic spinal cord injury (eWALK2.0)

Professor Jane Butler

Participation in other future studies

We may invite you to participate in **other** future studies or, in rare instances, a media event related to the study. Please indicate below if you give Neuroscience Research Australia permission to contact you for this purpose.

- ☐ I give my permission for the de-identified data collected in this study to be used for future studies by the investigators.
- ☐ I give my permission for Neuroscience Research Australia to contact me in the future to ask if I would like to participate in future studies.
- ☐ I consent to be being contacted by the HREC-approved research staff about potential participation in media events.
- ☐ I consent to being filmed during part of my assessment or therapy session, which may be used for future presentations or publications.

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

Declaration by Researcher*

☐ I have given a verbal explanation of the research study; its study activities and risks and I believe that the participant has understood that explanation.

Researcher Signature*

Name of Researcher (please print)	
Signature of Researcher	
Date	

+An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study.

Note: All parties signing the consent section must date their own signature.

Neuroscience Research Australia ABN 94 050 110 346
Margarete Ainsworth Building
139 Barker Street (PO Box 1165)
Randwick Sydney NSW 2031 Australia
T +61 2 9399 1000 F +61 2 9399 1005
neura.edu.au

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Transcutaneous spinal cord stimulation combined with locomotor training to improve walking ability in people with chronic spinal cord injury (eWALK2.0)

Professor Jane Butler

Form for Withdrawal of Participation

You have told the study team or your clinician that you would like to withdraw from the study. You have the right to withdraw fully from this study at any time and you do not have to give a reason. However it is possible to withdraw only from certain parts of the study, and we would be grateful if you would consider the different options. Withdrawing fully or partly will not affect your relationship with the University of New South Wales or NeuRA.

Read this form carefully. Ask a member of the study team if you have any concerns and make sure you receive answers to your questions before you sign. Your participation in the study remains confidential and results will only be available as outlined in the consent form you signed at the start of the study.

Please discuss your options and intentions with your clinician, study staff and relatives before withdrawing. You have many options for continuing in the study. It is important for the staff to understand exactly which aspects of the study you wish to discontinue.

WITHDRAWAL OPTIONS

Please tick one:

I want to take part in the remaining training sessions	Yes ☐ No ☐
I want to take part in the remaining assessments	Yes ☐ No ☐
I allow my personal information collected during the study to be used for its intended purpose	Yes ☐ No ☐

I confirm that I have had enough time to review this form and all my concerns and questions have been answered to my satisfaction. I withdraw my consent for participation in this study in accordance with the withdrawal option I have selected above.

Participant Signature

Name of Participant (please print)	
Signature of Participant	
Date	

The section for Withdrawal of Participation should be forwarded to:

Name:	Professor Jane Butler
Email:	j.butler@neura.edu.au
Phone:	9399 1608
Postal Address:	NeuRA, 139 Barker St, Randwick NSW 2031

Neuroscience Research Australia ABN 94 050 110 346
Margarete Ainsworth Building
139 Barker Street (PO Box 1165)
Randwick Sydney NSW 2031 Australia
T +61 2 9399 1000 F +61 2 9399 1005
neura.edu.au