Spinal cord electrical stimulation: can it improve walking ability in people with SCI?

eWALK

Dr Claire Boswell-Ruys and Dr Elizabeth Bye

Spinal cord electrical stimulation: can it really improve walking ability in people with SCI?

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Transcutaneous spinal cord stimulation combined with locomotor training to improve walking ability in people with chronic spinal cord injury: a multi-centre double-blinded randomised sham-controlled trial

The eWALK trial

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Neuroscience Research Australia

SpinalCure AUSTRALIA

CATWALK Funding research to cure spinal cord injury

NeuRA Discover. Conquer. Cure.

Spinal Cord Injury Research Centre

Research team

- Professor Simon Gandevia (Chief Investigator)
- Professor Jane Butler
- Dr Euan McCaughey
- Dr Claire Boswell-Ruys
- Dr Martin Héroux
- Dr Bonne Lee
- Dr Elizabeth Bye

Background

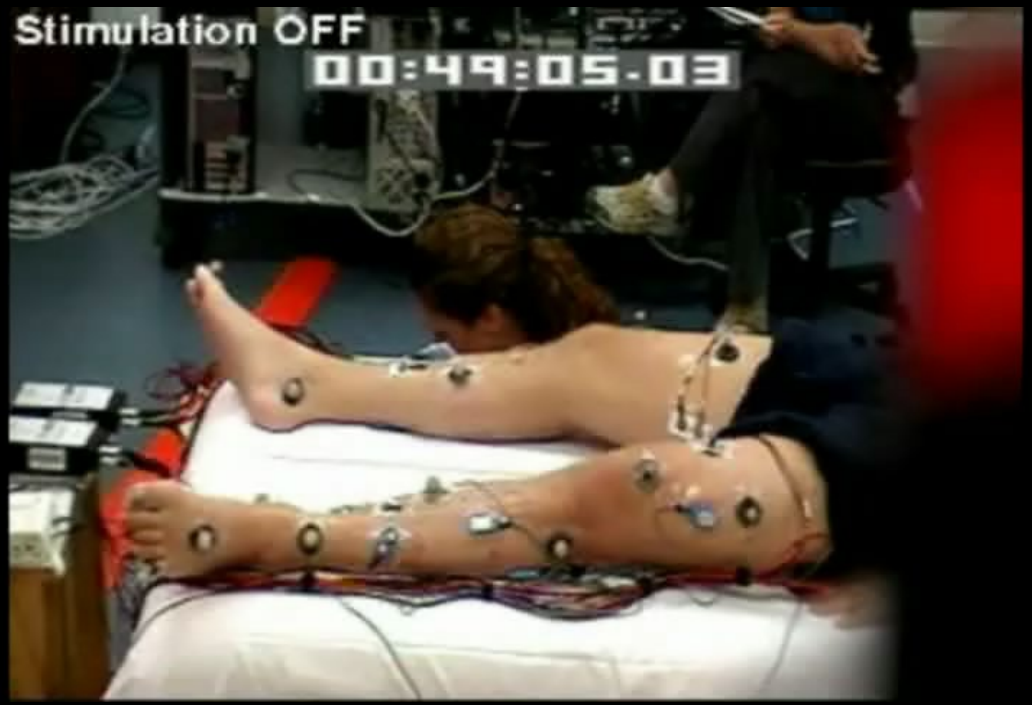
- Walking is a high priority for people following a spinal cord injury (SCI)
- No treatments currently available to restore voluntary control

Recent developments

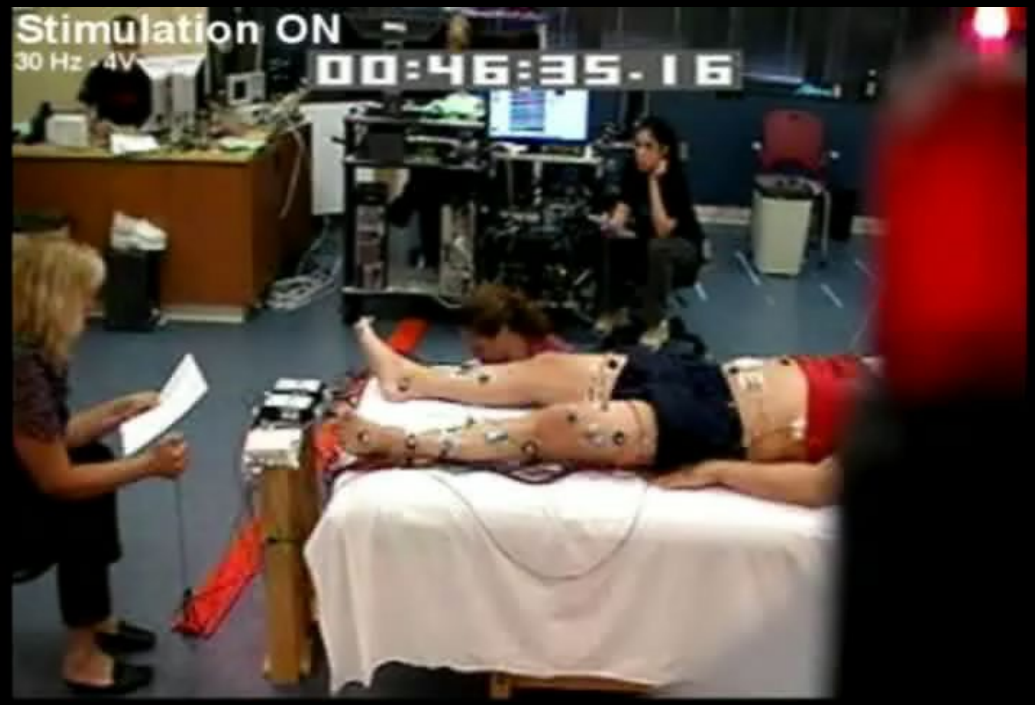
- Epidural and transcutaneous electrical stimulation of the spinal cord may be able to restore voluntary movement in some people with SCI
- Implantation of electrodes in the spinal cord is an invasive and costly surgical procedure
- Transcutaneous spinal stimulation (TSS) is cheaper and of lower risk, and preliminary data shows similar results to epidural stimulation

Background

- A study published in The Lancet in 2011 by Harkema et al outlined a case study of a person with motor complete paraplegia receiving epidural stimulation



Stimulation off



Stimulation on

Harkema et al 2011

Background

- Some dramatic effects in a number of small cases

Sayenko et al 2019

Background

Sayenko et al 2019

Limitations of previous studies

- Small sample sizes
- No strict inclusion/exclusion criteria used (hand-picked participants)
- Unblinded, non-randomised, no control/sham = bias
- No standardised therapeutic intensities
- Differences in electrode position
- Differences in stimulation and locomotor protocols

Aim

- To determine whether 12 weeks of transcutaneous spinal stimulation combined with locomotor training can improve walking ability in people with spinal cord injury (SCI).

Methods - design

- Double blinded, randomised sham-controlled trial
- Multi-centred international trial
- N=50
- Stimulation sites and parameters standardised
- 12 week intervention of spinal or sham stimulation combined with locomotor training
- 4 week follow up
- Assessors, therapists and participants will all be blinded
- Trial registration ACTRN12620001241921

Methods - inclusion criteria

- SCI sustained a minimum of 12 months prior to consent
- Bilateral motor levels from T1 to T11
- Walking Index for SCI II (WISCI II) from 1 to 6
- Voluntary muscle contraction in at least one lower limb muscle
- Deemed medically stable to undertake the program
- Aged 16 years or over

Methods - exclusion criteria

- History of clinically significant AD in response to electrical stimulation
- Unable to tolerate transcutaneous spinal stimulation at a therapeutic intensity
- History of hypotension in response to standing
- Progressive neurological disease or any other major neurological lesion
- Syrinx on recent MRI
- Open surgery within the last 3 months
- Unable to elicit reflexes whilst experiencing the stimulation suggesting a lower motor neurone lesion
- Severe spasticity
- Extensive contractures
- Existing pressure ulcer Stage 3 or 4
- Myocutaneous flap using a graft from a locomotor muscle such as the gluteals
- Any contraindications to electrical stimulation such a pacemaker, pregnancy
- An upper limb injury preventing prolonged weight bearing
- Stem cell or olfactory ensheathing cell therapy within the last 5 years
- Actively participating, or are in the follow-up period, of any other clinical trial

Primary outcome measure

- Walking ability with stimulation measured using the WISCI II

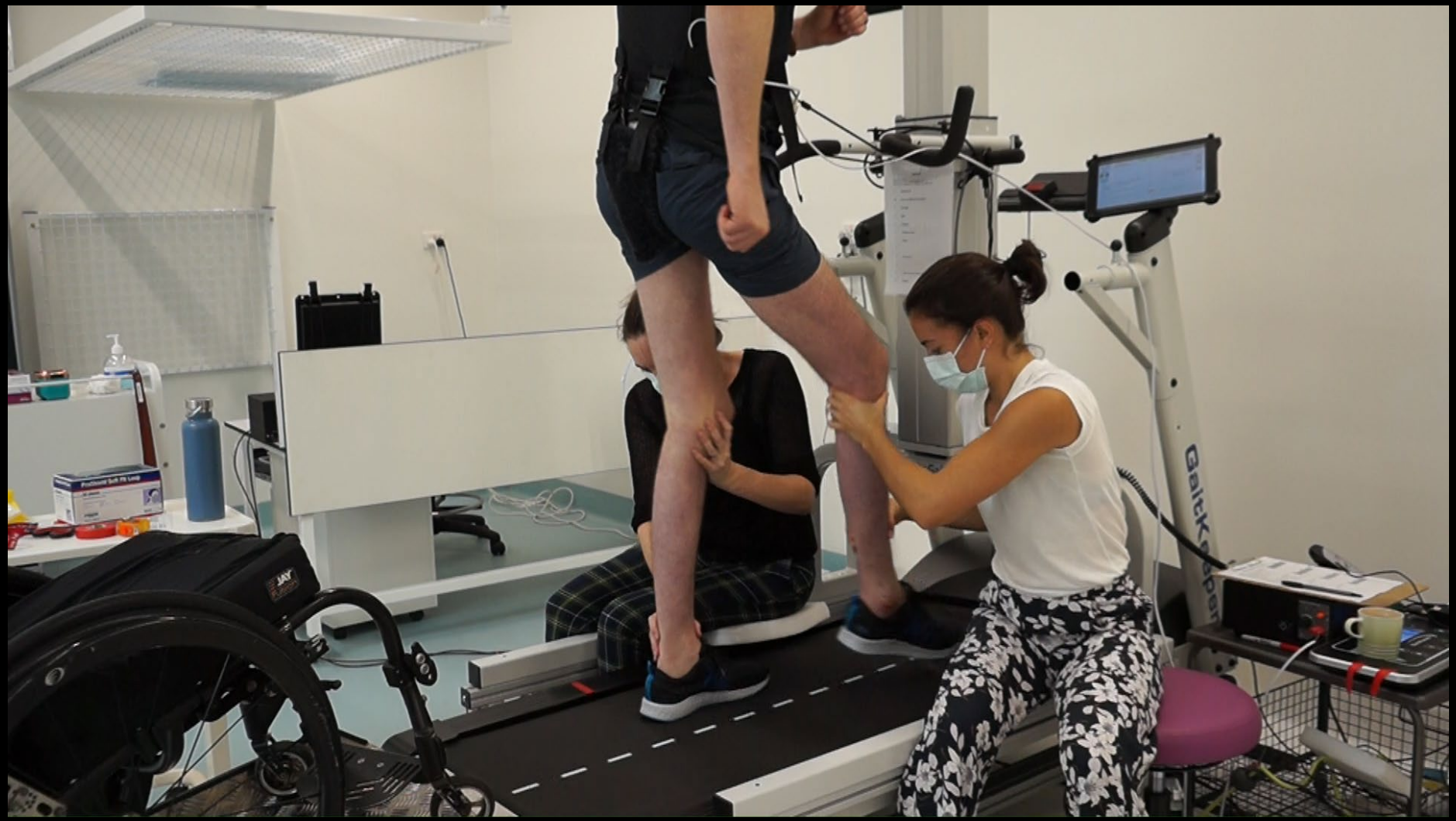
Secondary outcome measures

- Walking ability without stimulation (WISCI II)
- Sensation (C2 - S4-5) without stimulation
- Lower extremity motor function with and without stimulation
- Spasticity with and without stimulation
- Bowel function – Neurogenic Bowel Dysfunction questionnaire
- Quality of life – EQ-5D-5L questionnaire

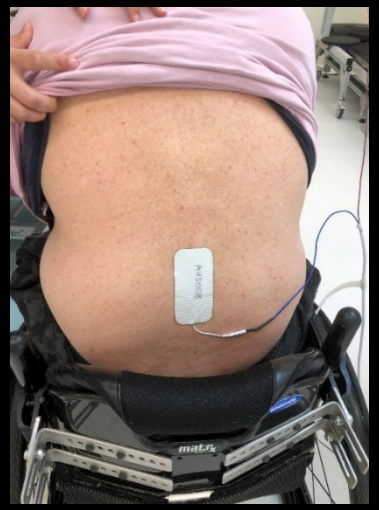
Intervention

- 12 weeks, 3x/week
- 30 minutes of stimulation/sham combined with locomotor training
- All sessions on a treadmill, except one is done every second week ‘overground’
- Delivered by one experienced spinal physiotherapist and up to two assistants

Locomotor training



Transcutaneous spinal stimulation

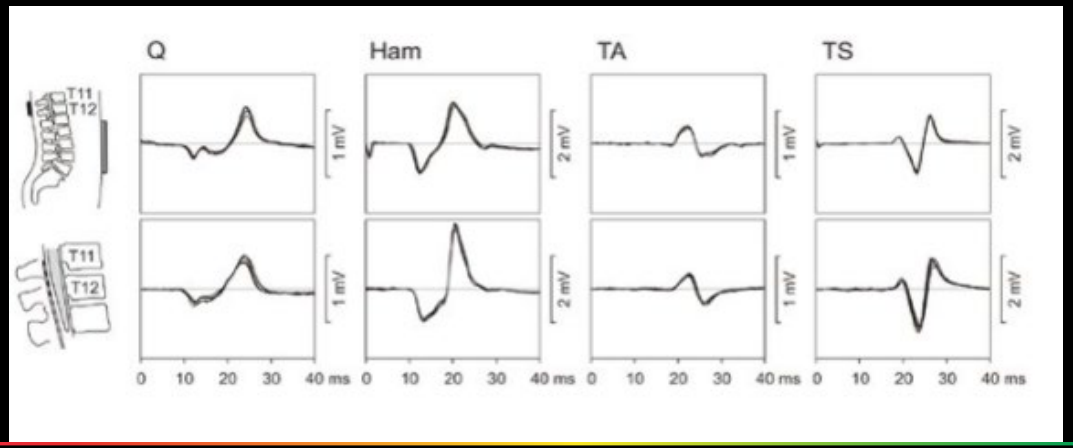


- Cathode electrode (5x10cm) over lower back (top edge at L1-L2 interspace)
- Anode electrode (5x10cm) over lower abdomen

- Custom controller drives a Digitimer stimulator (DS8R)
- During training, stimulation is continuous at 20Hz with 10kHz carrier frequency

Setting the stimulus intensity using evoked reflexes

- Posterior-root muscle (PRM) reflexes are evoked muscle responses elicited by electrical stimulation of posterior nerve roots of the spinal cord
- Single pulses of 1ms are delivered at increasing intensities
- Minimal stimulation intensity required to induce PRM reflexes in vastus medialis muscles is determined
- Target stimulus intensity for training sessions is 100% of that determined during reflex testing
- Intensity is re-assessed every two weeks and the intensity for training adjusted



Hofstoetter et al 2014

Sham stimulation

- Set-up, procedures and training will be identical for participants randomised to the Sham group, except that they will receive sham stimulation during training
- All participants will be blinded to their group allocation
- Details of the novel sham stimulation will be reported with trial results

Current status

- Screened 28 people
- Two participants have completed 12 week program and one has performed follow-up
- One active in trial
- Two waiting to commence (no enrolment during lockdown)
- Two waiting for medical clearance
- Setting up international sites

Further Information

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Further Information

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