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SUMMARY OF PROJECT UP STIM: using spinal cord stimulation to enhance upper limb rehabilitation in those individuals who have an acute spinal cord injury

Abstract: *Cervical spinal cord injury (SCI) is a high break in the spinal cord, which impairs all motor and sensory function below the level of injury, including trunk and lower limb activity as well as arm and hand function. This substantially limits the affected individual's ability to carry out daily functional tasks and to live independently. Recovering hand and arm function is a top priority among people living with cervical SCI.*

Transcutaneous spinal cord stimulation (tSCS) enables volitional motor control over otherwise paralysed muscles in people with chronic SCI, sometimes leading to functional recovery. Applying this simple, low-cost technique much earlier in the recovery and treatment of the patient will benefit early functional recovery.

In this pilot Randomised Controlled Trial (RCT), tSCS combined with inpatient rehabilitation will be compared to sham-tSCS. If upper limb recovery is significantly greater in the tSCS group, this will provide strong scientific evidence to support the effectiveness of tSCS. Outcome measures include upper limb function, spasticity, patient-assessed outcomes and neurophysiology.

Background: In the UK, there are more than 1000 new cases of spinal cord injury (SCI) each year, with >50 % of these affecting the cervical spine. People who have reduced sensory and motor function affecting their upper limbs may have difficulty carrying out activities of daily living, significantly affecting their independence. Recovering even partial upper limb function is a top priority among tetraplegics.

Transcutaneous Spinal Cord Stimulation (tSCS) involves the application of continuous electrical stimulation over the back of the neck, targeting nerves from arm and hand muscle as they enter the spinal cord. Animal research has shown that tSCS modulates activity in upper limb spinal circuitry, enabling weak signals from the

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brain to reach hand and arm muscles. Early human trials with tSCS have provided remarkable results: people with long-standing cervical SCI regained arm and hand movement after adding tSCS to rehabilitation sessions, improving independence and re-enabling performance of fine motor tasks such as playing guitar.

A clinical trial in Scotland was recently publicised after a former rugby player who had a cervical SCI >20 years ago became able to hold a mobile phone for the first time after participating in the tSCS trial.

The potential for motor recovery after SCI is maximal in the first 6 months' after injury. During this time, inpatient rehabilitation is focussed on practicing upper limb functional and fine motor tasks, with the goal of optimising independence after discharge. Applying tSCS during early rehabilitation is likely to lead to even greater functional recovery than has been found in people with chronic injuries. Following our previous INSPIRE Foundation-funded trial, Stim2Stand, the RNOH have approved tSCS for both upper and lower limb rehabilitation in compassionate cases and we are the first group to have trialled tSCS during early, inpatient rehabilitation.

Our case studies of inpatients at the RNOH include a 20-year-old patient (C4 AIS A), where new activity was seen in their first tSCS session. The patient was able to activate bilateral triceps, thumb and fingers when tSCS was applied at 30 Hz, 1 ms biphasic pulses, up to 70 mA for 20 minutes.

The patient purchased their own stimulator following discharge, and has since reported activation of the quadriceps with stimulation. A second case study (29-year-old, T12, AIS B), who had flickers in bilateral quadriceps (without tSCS) achieved anti-gravity quadriceps activation when tSCS was applied up to 40 mA for 20 minutes. For this patient, tSCS was used during standing activities in a supportive frame, where they were able to carry out weight-shifts and mini squats. For the NHS to offer tSCS as part of standard rehabilitation, stronger evidence of its effectiveness is required, through a randomised controlled trial (RCT).

In this project, we will conduct a pilot RCT; tSCS combined with inpatient rehabilitation will be compared to sham-tSCS in order to control for any placebo effects.

What will this study aim to achieve for the SCI individual? Our ultimate goal is to provide strong scientific evidence to support the effectiveness of tSCS by showing that upper limb recovery is significantly greater in the tSCS group compared to the sham-tSCS (placebo) group. The current project is a single-site pilot RCT. If successful, we intend to expand the trial into an adequately powered multi-site RCT. The aims of this project are;

1) To investigate the feasibility and acceptability of; (i) adding tSCS to inpatient rehabilitation in people with acute SCI and; (ii) randomising people undergoing inpatient rehabilitation into tSCS and sham-tSCS groups (primary aim).

2) To measure the effects of adding tSCS compared with sham-tSCS to regular inpatient rehabilitation sessions on ISNC-SCI motor and sensory scores at discharge and up to 1-year post-injury.
3) To explore the underlying mechanisms which may contribute towards functional recovery when tSCS is added to inpatient rehabilitation.
4) To explore the effects of stimulation parameters (pulse width, frequency) and electrode placement on corticospinal excitability in healthy participants.

More about the Team:

1. Team Leader and Principal Investigator: **Dr Lynsey Duffell**. You can find out more about Lynsey at https://www.researchgate.net/profile/Lynsey-Duffell and here she is speaking at last year's IMech Conference on 'Incontinence – The Engineering Challenge in Bristol in 2023:

2. **Sue Paddison**, Clinical Specialist Physiotherapist and Team Lead at The London Spinal Cord Injury Centre/Royal National Orthopaedic Hospital. Sue has many years' experience as a specialist physiotherapist and has seen the excellent results of early intervention in treatment of spinal cord injured patients. Sue qualified as a Physiotherapist in 1986 and developed her

career in Acute Trauma and Orthopaedics. She became a Superintendent Physiotherapist in the NHS specialising in Trauma and Orthopaedics in 1993. She moved to her current post as Superintendent/ Lead Clinical Specialist physiotherapist in the London Spinal Cord Injuries Centre at the Royal National Orthopaedic Hospital Trust, Stanmore in 1993.