

Transcutaneous spinal cord stimulation combined with activity-based therapy leads to sensorimotor improvements in chronic, thoracic spinal cord injuries

A pilot study

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Background

Spinal Cord Injury (SCI) often results in neurological impairment of the trunk, significantly impacting proximal stability required for various movements, ranging from minor weight shifts to large distal movements of the extremities. Qualitative improvements in trunk stability can enhance sensorimotor and autonomic function, thereby improving the overall quality of life for individuals with SCI. These improvements correlate with increased functional independence, potentially leading to reduced care costs over an individual’s lifespan.

Study Overview

This pilot study aimed to assess the effects of non-invasive transcutaneous spinal cord stimulation (tSCS) delivered using the LIFT device (ARCE^{EX} Therapy) (ONWARD Medical, Eindhoven, Netherlands), in conjunction with activity-based therapy (ABT) over an extended treatment period (120 sessions spanning one year). The study focused on evaluating the impact of this combination on sensorimotor function and functional independence in individuals with chronic SCI.

A sub-cohort of five individuals with chronic thoracic SCI, drawn from a broader clinical trial, was recruited from two Neurokinex centers (Hemel Hempstead and Gatwick, UK) and is included in the current analysis. Participants visited the rehab center an average of three times per week for one year, completing a total of 120 sessions of ABT with tSCS delivered over the thoracolumbar spine (tSCS-ABT). Outcome measures were obtained at several different time points.

Participant	Age	Sex	Time since injury	AIS Level of Injury At baseline	AIS Level of Injury After 120 tSCS-ABT	AIS Classification At baseline	AIS Classification After 120 tSCS-ABT
G1	30	M	3 years	T10	T11	B	C
G2	26	M	3 years	T6	T6	C	D
H2	37	M	8 years	T12	T12	A	C
H3	44	F	2 years	T6	T11	D	D
G4	37	M	2 years	T10	T11	A	A

Table 1 – Participant demographics and changes in American Spinal Injury Association impairment scale (AIS).

ACTIVITY-BASED THERAPY WITH TRANSCUTANEOUS ELECTRICAL STIMULATION OF THE SPINAL CORD	
ACTIVITY-BASED THERAPY	tSCS
<ul style="list-style-type: none">3 rehab sessions per week2 hours per session45+ minutes of tSCS per sessionExercises for trunk and lower extremity function (i.e., static and dynamic sitting balance, trunk extension/ flexion/ rotation, active/supported standing)All exercises were individualized according to the needs and functional status of the participantAll exercises were performed with volitional drive (will power)	<ul style="list-style-type: none">LIFT device (ARCE^{EX} Therapy) (ONWARD Medical)Monophasic 1 ms pulse3 mA to 45 mA30 Hz frequency10 kHz carrier frequencySingle or multi-site stimulation (T10 to L5)Parameters adjusted with comfort and functional improvements

Table 2 – Parameters of active-assisted exercises (activity-based therapy) combined with transcutaneous electrical stimulation of the spinal cord.

OUTCOME MEASURES	TIME POINTS
<ul style="list-style-type: none">ISNCSCI ASIA Impairment Scale (AIS)Quality of Life (WHOQOL-BREF)Spinal Cord Injury Independence Measure (SCIM III)	<ul style="list-style-type: none">BaselineAfter 40 sessionsAfter 120 sessions
<ul style="list-style-type: none">NeuroRecovery Scale (NRS)	<ul style="list-style-type: none">BaselineEvery 20 sessions until completion

Table 3 – Outcome measures and corresponding time points.

Results

NRS scores

After 120 sessions of tSCS-ABT, NRS-Total and NRS-Trunk significantly improved ($\Delta 1.1$ (95% CI 0.2–1.9) and $\Delta 2.3$ (95% CI 1.2–3.3)) with improvement dependent upon training dosage.

ISNCSCI scores

After 120 sessions of tSCS-ABT, ISNCSCI sensation to pinprick ($\Delta 2.8$ (1.9), (95% CI 0.4–5.2), $p < 0.05$) and light touch ($\Delta 1.8$ (0.8), (95% CI 0.8–2.8), $p < 0.01$) improved.

Quality of Life and Independence scores

- Modest but not significant improvements in scores across the physical, psychological health and social relationships WHOQOL-BREF domains. Slight but not significant decrease in the environment domain.
- Unchanged SCIM III scores.

Additional outcomes

- Improvement in ASIA Impairment Scale (AIS) classifications for 3 participants.
- Changes in level of injury for 3 participants.
- All 120 sessions were completed with at least 45 minutes of continuous tSCS.
- No significant adverse events.

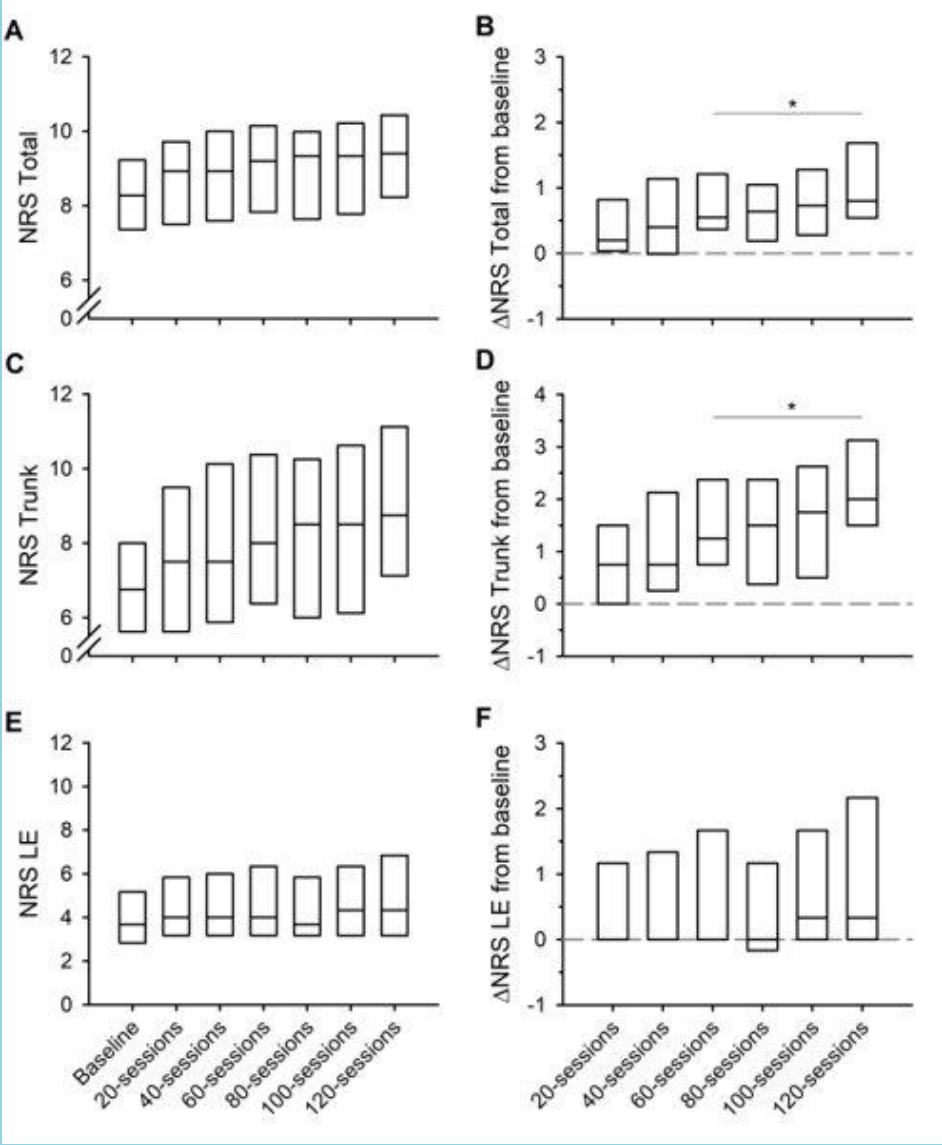


Fig. 1 – NeuroRecovery Scale (NRS) scores. Left panels displays group (n = 5) average (mean ± SE) NRS scores obtained at baseline, 20, 40, 60, 80, 100 and 120 sessions of tSCS-ABT and right panel displays the group average (± 95% CI) for the change in NRS scores from baseline after 20, 40, 60, 80, 100 and 120 sessions, for NRS-Total (A & B), NRS-Trunk (C & D) and NRS-LE scores (E & F). * denotes $p < 0.05$.

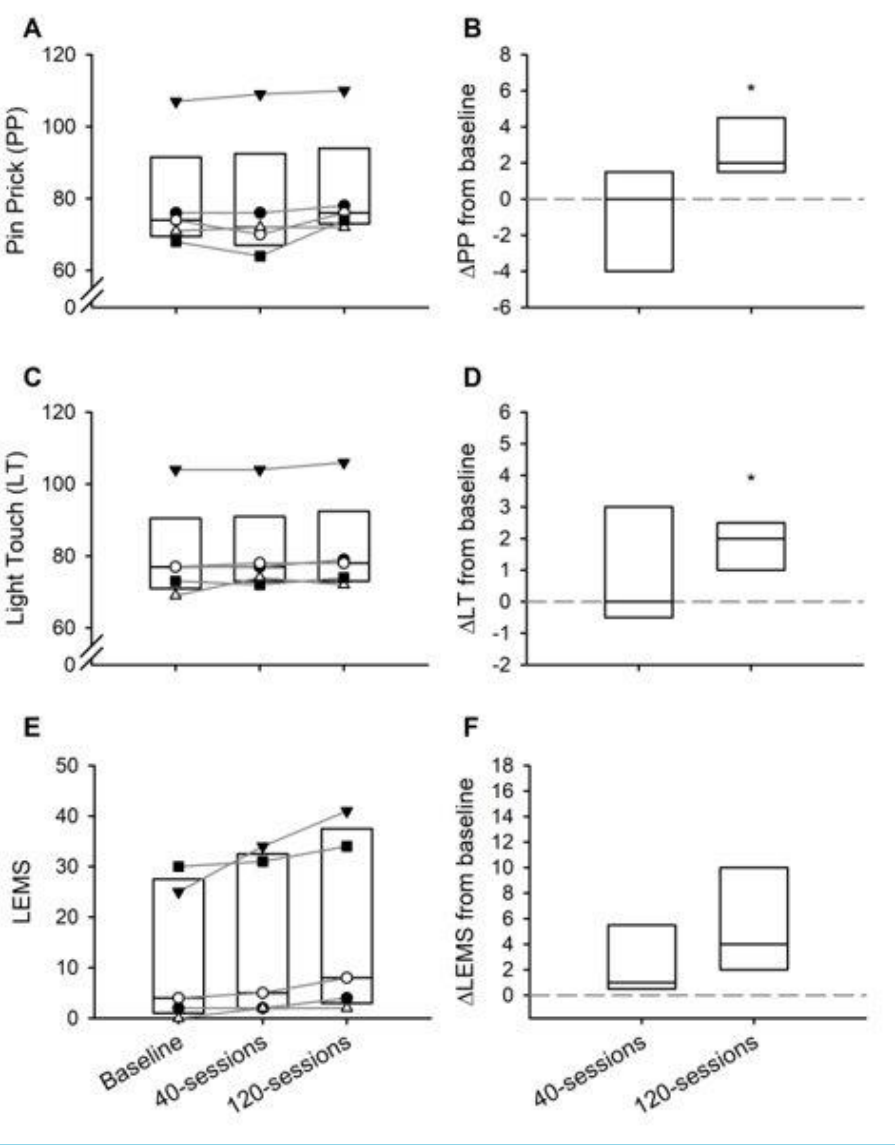


Fig. 2 – AIS Motor and Sensory scores. A, C, E) Left panel displays group average (mean ± SE) Pin Prick (A), Light Touch (C) and Lower Extremity Motor (LEM) scores (E) at baseline and following 40 and 120 sessions. B, D, F) Right panel displays the group average (± 95% CI) of the change in baseline for Pin Prick (B), Light Touch (D) and LEM scores (F) following 40 and 120 sessions. * denotes $p < 0.05$.

Conclusion & Perspectives

Sub-threshold thoracolumbar tSCS in combination with activity-based therapy was found to be tolerated for a prolonged time period in a small group of participants, with no report of serious or unexpected adverse events. Participants adherence to the intensive study protocol demonstrate the practicality of its application in community-based, outpatient clinical settings.

Sensorimotor function improvements were made after a minimum of 60 sessions tSCS-ABT when delivered at 30 Hz frequency and amplitude below the threshold of motor activation. Outcome measures were assessed without the presence or prior application of tSCS on the day of testing, supporting the notion that improvements in clinical functional outcomes were driven by neuroplastic changes induced by the intervention rather than any acute neuromodulatory effects of tSCS. As significant incremental improvements in function continued after 120 sessions, trends suggest that prolonged training with tSCS-ABT is an effective neuromodulation intervention for individuals with SCI and may enable further improvements.