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Research

# Early intensive hand rehabilitation is not more effective than usual care plus one-to-one hand therapy in people with sub-acute spinal cord injury ('Hands On'): a randomised trial

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KEY WORDS

Spinal cord injury
Hand therapy
Rehabilitation
Physical therapy
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ABSTRACT

**Question:** What is the effect of adding an intensive task-specific hand-training program involving functional electrical stimulation to a combination of usual care plus three 15-minute sessions per week of one-to-one hand therapy in people with sub-acute tetraplegia? **Design:** A parallel group, randomised, controlled trial. Participants were randomly assigned (1:1) via a computer-generated concealed block randomisation procedure to either a control or experimental intervention. **Participants:** Seventy people with C2 to T1 motor complete or incomplete tetraplegia within 6 months of injury. Participants were recruited from seven spinal units in Australia and New Zealand. **Intervention:** Experimental participants received intensive training for one hand. Intensive training consisted of training with an instrumented exercise workstation in conjunction with functional electrical stimulation for 1 hour per day, 5 days per week for 8 weeks. Both groups received usual care and 15 minutes of one-to-one hand therapy three times per week without functional electrical stimulation. **Outcome measures:** The primary outcome was the modified Action Research Arm Test reflecting arm and hand function, which was assessed at the end of the intervention, that is, 11 weeks after randomisation. Secondary outcomes were measured at 11 and 26 weeks. **Results:** Sixty-six (94%) participants completed the post-intervention assessment and were included in the primary intention-to-treat analysis. The mean modified Action Research Arm Test score for experimental and control participants at the post-intervention assessment was 36.5 points (SD 16.0) and 33.2 points (SD 17.5), respectively, with an adjusted mean between-group difference of 0.9 points (95% CI –4.1 to 5.9). **Conclusion:** Adding an intensive task-specific hand-training program involving functional electrical stimulation to a combination of usual care plus three 15-minute sessions per week of one-to-one hand therapy does not improve hand function in people with sub-acute tetraplegia. **Registration:** Australian and New Zealand Trial Registry ACTRN12609000695202 and ClinicalTrials.gov NCT01086930. **[Harvey LA, Dunlop SA, Churilov L, Galea MP, Spinal Cord Injury Physical Activity (SCIPA) Hands On Trial Collaborators (2016) Early intensive hand rehabilitation is not more effective than usual care plus one-to-one hand therapy in people with sub-acute spinal cord injury ('Hands On'): a randomised trial. *Journal of Physiotherapy* 62: 88–95]**



## Introduction

People with tetraplegia consider loss of hand function to be more debilitating and limiting on quality of life than any other consequence of spinal cord injury (SCI), including the inability to walk or control bladder and bowel function.[1] Research attention in recent years has therefore appropriately focused on identifying possible ways of improving the hand function of people with tetraplegia. Intensive task-specific training with sensory or functional electrical stimulation (FES) is one of many interventions that has received research attention, with initial promising results, but it has not been examined within a large, high-quality clinical trial.[2–4] It has been hypothesised that intensive task-specific training with FES improves neural recovery and motor control following SCI. The combination of therapies provides both sensory input from the periphery and motor input from the sensorimotor cortex onto the damaged spinal cord. It is believed that neural bombardment from these two sources may promote neural

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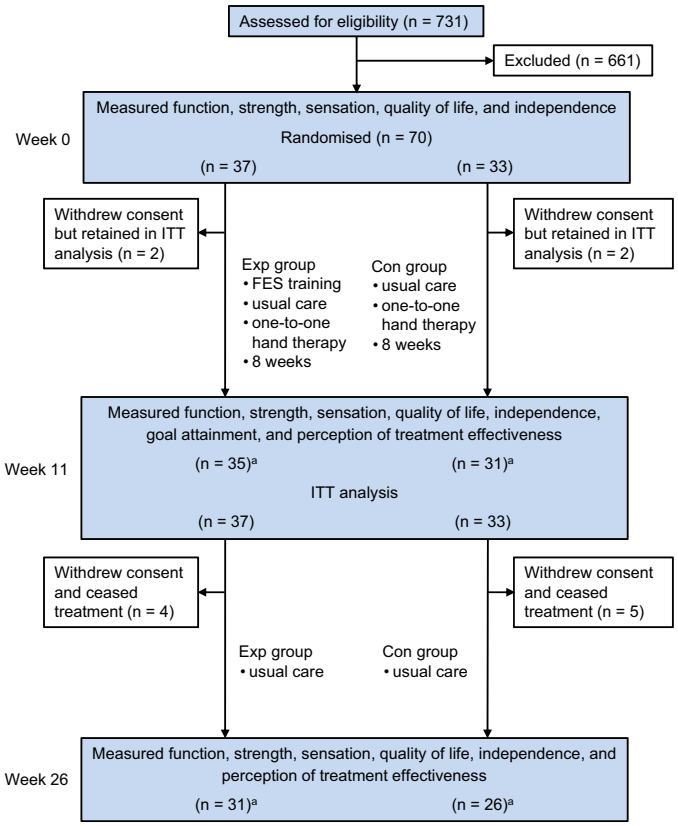
plasticity and provide the critical stimulus required to elicit neurophysiologic and structural re-organisation of the relevant pathways.[5]

One of the difficulties with providing intensive task-specific practice is that training is not always well tolerated by participants because repeatedly practising the same movement outside a functional context can be tedious. Increasingly, technology has been used to try to overcome this barrier (eg, commercially available, computerised video games that respond to body motion are used to practise balance in people with stroke).[6] For the present trial, a similar concept was wanted for the hand, but since there were no appropriate motion-controlled video devices or games for training hand function in people with tetraplegia, we used FES and an instrumented exercise workstation incorporating several types of manipulanda connected to a computer[a]. Participants triggered FES to drive the different types of hand grasps (eg, pinch, squeeze, grasp, twist, lift, push or pull) required for playing the computer games.[7] The FES was triggered with a behind-the-ear bluetooth device[a] that is sensitive to tooth clicks. The technology thus provided a way of encouraging patients to perform large numbers of different hand movements within a dynamic environment. There is preliminary evidence from five studies to suggest that this technology may be therapeutic.[3,4,8–10] However, all these studies are small and have methodological flaws exposing them to bias.

Therefore, the questions for this parallel group, randomised, controlled trial were:

1. Is adding an intensive hand-training program, with an instrumented exercise workstation and functional electrical stimulation, to usual care more effective than usual care alone in people with sub-acute tetraplegia?
2. What are the possible benefits on muscle strength, sensation, function and quality of life?




ITT = intention-to-treat; con = control, exp = experimental

**Figure 1.** CONSORT flow chart indicating the number of participants screened, randomised and included in intention-to-treat analysis ([a] some participants did not complete all assessments. See Table 2 for details).

## Method

### *Design*

A multi-centre, randomised, assessor-blinded, phase-3 trial was undertaken on inpatients at seven SCI units in Australia and New Zealand. Participants were randomised to the experimental or control group. Experimental participants received an intensive 8-week hand-training program for the target hand. Participant recruitment commenced 23 November 2009 and finished 31 December 2013. The trial protocol (including full details of the study rationale, design and statistical analysis) was published and is available online.[11] The trial was managed by a professional clinical trial management company[b] and overseen by an independent data safety monitoring committee.

### *Participants, therapists and centres*

Seventy participants with sub-acute tetraplegia undergoing inpatient rehabilitation in one of the seven participating SCI units were recruited from a consecutive sample of admissions (Figure 1). The hospital therapists screened participants for suitability and then enrolled them in the study. These therapists provided usual care to all participants but were not otherwise involved in the trial. Instead, specifically designated trial therapists administered the intervention to the experimental participants. One hand of each participant was identified as the target hand according to the criteria below. In situations where both hands met the inclusion criteria, the hospital therapist selected the hand deemed most likely to benefit from intensive training.

Participants were included if they: were 16 years or older and had sustained a motor complete or incomplete SCI at the neurological level of C2 to T1 within the preceding 6 months; were likely to remain in hospital for 12 weeks; had a reduced ability to grasp with the target hand, as determined by the clinical judgement of the hospital therapist; and were able to tolerate sufficient FES to enable the target hand to grasp and release. Participants were excluded if they had a pre-existing injury to the hand or upper limb or any condition that precluded use of the exercise workstation and FES (the full inclusion and exclusion criteria are detailed in the protocol).[11]

The trial statistician used a computer random number generator to create the randomisation schedule, which was stratified by site and the baseline score of the modified Action Research Arm Test (m-ARAT; $\leq 21$ versus $> 21$) using permuted blocks of random sizes. To ensure concealment, block sizes were undisclosed. An independent researcher with no clinical involvement in the trial randomly assigned the participants to either the control or experimental group with a 1:1 ratio. After completion of baseline assessments, randomisation was performed by an administrator who was independent of the recruitment process and located off site[b] to ensure concealment. A participant was considered to have entered the trial once his/her randomisation was allocated.

Trial and hospital therapists and participants were unblinded, but the assessors and statisticians performing the analyses were blinded. The success of assessor blinding was checked by asking assessors whether they had been unblinded.

### *Intervention*

Experimental participants received training directed at the target hand five times per week for 8 weeks commencing 3 weeks after randomisation. The 3-week delay in commencing the intensive training was required to allow time for the delivery of the FES garments for the experimental participants. The training consisted of an intensive task-specific hand-training program provided through an instrumented exercise workstation[a] in