Safety and efficacy of intensive task-specific training in people with recent spinal cord injury: a phase 3, pragmatic, randomised, assessor-blinded, superiority trial

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Summary

Background **It is widely believed that intensive task-specific training enhances neurological recovery in people with spinal cord injury (SCI) by exploiting activity-dependent spinal plasticity. We aimed to determine whether 10 weeks of intensive task-specific training supplemented with strength training that targets motor function at and below the level of the lesion improves recovery following recent SCI.**

Methods **We conducted a pragmatic phase 3 superiority randomised controlled trial at 15 hospitals in Australia, Belgium, Italy, the Netherlands, Norway, and the UK (England and Scotland). People who sustained a SCI in the preceding 10 weeks, had some motor function below the level of injury, and were receiving inpatient rehabilitation were randomly assigned to usual care (control group) or usual care plus 12 h per week for 10 weeks of intensive task-specific training targeting voluntary motor function below the level of the lesion supplemented with strength training (intervention group). Randomisation was computer generated, concealed, and stratified by site and level of injury. The primary outcome was Total Motor Score of the International Standards for the Neurological Classification of SCI (0–100 points) at 10 weeks. The outcome assessors were blinded to group assignment. Serious adverse events were defined as those resulting in death, life-threatening conditions, prolongation of hospitalisation, or substantial disability. All analyses were conducted by intention to treat. The trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12621000091808; universal trial number: U1111-1264-1689).**

Findings **Between June 7, 2021, and Feb 5, 2025, 220 participants were randomly assigned to the control (n=111; 23 female and 88 male) or intervention (n=109; 28 female and 81 male) group. Data were available for 216 (98%) of 220 participants at 10 weeks (107 in the intervention group and 109 in the control group). The mean Total Motor Scores at 10 weeks were 78·76 (SD 17·34) for the control group and 78·36 (SD 17·00) for the intervention group. The mean between-group difference was 0·93 (95% CI –1·63 to 3·48; p=0·48). There were four serious adverse events (three in the intervention group and one in the control group) including two deaths in participants from the intervention group.**

Interpretation **Intensive task-specific training supplemented with strength training provided in people with recent SCI did not result in significant benefits on our primary and secondary clinical outcomes. The evidence does not support any beneficial effect of additional training for those receiving usual inpatient rehabilitation care from a multi-disciplinary team.**

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Introduction

There is a widely-held belief that people with spinal cord injury (SCI) benefit from intensive therapy directed at promoting neurological recovery, and that more therapy is better.[1] The type of therapy that has attracted the most attention incorporates the principles of task-specific training directed at regaining movement in paralysed or partially paralysed muscles innervated below the level of injury.[2,3] Task-specific training involves active and repetitious practice of purposeful movements. It can be facilitated with the use of robotics, training devices, and electrical stimulation but these adjuncts to therapy are not essential and do not define task-specific training; they merely provide ways to help deliver it.

The current focus on intensive task-specific training is largely motivated by animal studies that have demonstrated activity-dependent neural plasticity of the spinal cord.[4] These studies have shown that repeated

Research in context

Evidence before this study
We searched MEDLINE, Embase, EBSCO CINAHL Plus, Physiotherapy Evidence Database, and the Cochrane Central Register of Controlled trials using the Ovid platform from inception until Aug 13, 2020 (before the commencement of this trial). The search was restricted to trials that enrolled participants with SCI using the following terms: parapl*, tetrapleg*, spinal cord*, spinal inj*, quadripleg* or paralys*. This was combined with the Cochrane sensitive search strategy for randomised controlled trials. Furthermore, we searched the reference lists of all identified randomised controlled trials and systematic reviews, and examined the recommendations of clinical practice guidelines. We only identified two trials with more than 100 participants (n=116 and n=146) that had investigated any physical intervention for individuals with SCI. We have since identified two additional large trials (n=106 and n=105). The four trials involved intensive training and had some components of task-specific training but did not evaluate whether intensive therapy, and particularly task-specific training that targets the muscles directly affected by SCI, improves neurological recovery. Yet, the National Institute for Healthcare Excellence Guidelines recommend intensive rehabilitation programmes for individuals with SCI and other injuries.

Added value of this study
To our knowledge, this is the largest randomised trial to test the efficacy of any rehabilitation intervention provided in individuals with recent SCI. The trial showed that the addition of 10 weeks of intensive task-specific training supplemented with strength training does not improve neurological recovery in individuals who are already receiving approximately 8 h of inpatient rehabilitation per week.

Implications of all the available evidence
Whereas animal studies demonstrate activity-dependent spinal plasticity, we were unable to show any therapeutic benefit of an intensive programme of task-specific training supplemented with strength training. This could indicate that individuals with SCI are already receiving the optimal dose of task-specific training as part of usual inpatient rehabilitation rendering additional therapy redundant and that patients can be reassured that the usual amount of physiotherapy and occupational therapy is sufficient.

and intensive stepping[5–7] and attempts at purposeful movement[8] stimulate spinal plasticity and enhance neurological recovery. Similar responses to intensive task-specific training have been demonstrated in the brain following stroke and other neurological conditions.[9–11] These findings lend themselves to the argument that more practice of purposeful movement involving muscles directly affected by the SCI leads to better outcomes.[12] Consequently, attention has focused on maximising the amount of task-specific training provided to people with SCI[4,7,13] even though there is no direct evidence of the effectiveness of intensive therapy or of the optimal intensities or dosages of therapy.[1,5,14]

Few large trials have examined the effectiveness of any physical rehabilitation intervention for people with SCI. As part of an extensive search of the literature conducted during the development of the Australian and New Zealand Clinical Practice Guidelines for the Physiotherapy Management of People with SCI,[15] which we recently updated, we only identified four trials with more than 100 participants (105, 106, 116 and 146 participants). None has looked at the effectiveness of task-specific training provided in addition to usual care in people with recent SCI.[16–19] There are many smaller trials but most are vulnerable to bias and provide either inconclusive or conflicting results.[15] The recent National Institute for Health and Care Excellence (NICE) Guidelines recommend task-specific training. They also recommend intensive rehabilitation programmes for people with injuries such as SCI. This recommendation is based on expert opinion, not research evidence, and intensive is not quantified.[20] Other SCI-specific guidelines conclude there is no evidence that increasing the amount of rehabilitation does or does not improve outcomes.[14]

Evidence is needed to support or refute the prevailing belief that more physical rehabilitation is better and that the focus of therapy should be on repetitious task-specific training directed at regaining functional movement below the level of injury.[4,7,13] The evidence can be used to ensure people with SCI receive the best possible therapy and attain optimal outcomes. That is particularly important because intensive therapy is costly, and because people with SCI invest a large amount of time and effort pursuing these therapies.

The primary aim of this trial was, therefore, to determine whether supplementing usual inpatient rehabilitation (ie, usual care) following recent SCI with additional early and intensive task-specific training focusing on muscles directly affected by SCI enhances neurological recovery.[21] Secondary aims were to determine the effects of this intervention on function, ability to walk, quality of life, participants' perceptions about ability to perform self-selected goals, length of hospital stay, and participants' impressions of therapeutic benefit.

Methods

Study design
The Spinal Cord Injury Motor Training (SCI-MT) Trial was a pragmatic phase 3 superiority, double-blinded (assessors and statisticians) randomised trial. The trial was undertaken at 15 hospitals that provide rehabilitation

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to people with SCI in Australia (seven sites), Belgium (two sites), Italy (one site), the Netherlands (two sites), Norway (one site), and the UK (England [one site] and Scotland [one site]). All sites provided government-funded comprehensive multi-disciplinary inpatient rehabilitation for people with SCI. Approvals were initially obtained from the Ethics Committee of the Northern Sydney Local Health District (2020/ETH02540) and then subsequently from the relevant ethics committees in each involved site.[22] The trial protocol has been published.[22]

Participants

All patients admitted to the trial sites with a recent SCI were screened for inclusion by a site co-ordinator. Patients were eligible to participate in the trial if they were aged at least 16 years (except in two European sites [Ghent University Hospital, Ghent, Belgium and Foundation Santa Lucia, Rome, Italy] where the minimum age was 18 years), had sustained a traumatic or non-traumatic SCI in the preceding 10 weeks, and were likely to remain an inpatient for at least another 10 weeks. Potential participants needed to have some motor function below the neurological level of injury. That is, they needed to have an American Spinal Injuries Association Impairment (AIS) grade A with motor function more than three levels below the motor level (on one or both sides), or an AIS C or AIS D grade (as defined by the International Standards for the Neurological Classification of SCI). Potential participants were excluded if they had any substantial medical or physical condition (including pregnancy) or psychiatric illness that could prevent participation in the trial. The full inclusion and exclusion criteria are provided in the appendix (p 7) and can be found in the trial protocol.[22] Written informed consent was obtained from all participants. Demographic data were collected. Gender was self-reported (options: male, female, prefer not to answer, or self-describe in another way). Furthermore, the date in which a person first sat out of bed was collected from the medical charts to derive the time between injury and when the person first commenced mobilisation. These data were included to provide an indication of how long the participants had been on bedrest after injury.

See Online for appendix

Randomisation and masking

A blocked randomisation schedule stratified by site and level of injury (tetraplegia or paraplegia) that incorporated random permuted blocks was computer-generated by an independent statistician. The schedule was uploaded onto REDCap with strict control of user rights to ensure the randomisation schedule was concealed. Potential participants were approached by site investigators and invited to participate. A baseline assessment was then conducted, after which the site sent an email request for allocation. An offsite researcher who was otherwise not involved in the trial logged into the REDCap database, triggering the randomisation which sent an automated email notification to the local site investigator. Participants were randomised in a 1:1 ratio to either the control or intervention group. Participants allocated to the intervention group were prescribed 12 h of intensive motor training per week for 10 weeks in addition to usual care. Participants allocated to the control group received usual care alone. Randomisation occurred within 5 days of the baseline assessment, and the intervention commenced within 2 days of randomisation.

It was not possible to mask the participants or treating therapists to allocation. However, all assessors were masked. The success of masking was recorded by asking assessors to declare whether they had been inadvertently unmasked during the assessment. Most authors and investigators were also masked. The exceptions were the site investigators and two others (JC and JVG) who assisted with various logistical issues such as site payments, training of staff, and collection of Case Report Forms and other logs.

Procedures

Participants in the Intervention group received 12 h of intensive motor training per week for 10 weeks in addition to usual care. The motor training was provided on a one-to-one basis primarily with a physiotherapist but occasionally with an occupational therapist or exercise physiologist. The 12 h refers to the amount of time in therapy, not the amount of time actively engaged in training. Data were collected on the time in therapy, the time actively exercising, and the number of sessions that were attended. Training was commonly provided in six 2-h sessions from Monday to Saturday, but that was not mandated. The time participants devoted to actively engaging in training (as opposed to time spent in rest, talk, or setup) was captured using the International SCI Physical Therapy-Occupational Therapy Basic Data Set (ISCI PT-OT BDS).[23]

The motor training was individualised for each participant but had to be directed at muscles innervated below the level of injury and involve as much task-specific active practice of purposeful movements as possible. The emphasis was on repetitious practice within a structured training environment that incorporated the key principles of task-specific training (details of the intervention according to the Template for Intervention Description and Replication checklist are provided elsewhere[24]). This included the use of practice sheets to ensure targets were set for each exercise and training was progressed. The task-specific training was supplemented with strength training (we refer to the combination of task-specific training and strength training as motor training). Any training devices could be used, including treadmills, robotics, electrical stimulation, and walking aids or orthoses, provided they did not discourage patients from actively contracting muscles and contributing to attempts at movement, and provided they facilitated movement strategies that were similar to those used by their non-disabled counterparts. All therapists were trained and received a detailed study manual. Furthermore, therapists submitted participants' practice sheets to trial staff who regularly reviewed the sheets and provided feedback as required. The fidelity of the intervention was assessed in several ways. In brief, spot audits were conducted of randomly selected training sessions and record audits were conducted on 2868 practice sheets for 2912 sessions of 60 randomly selected participants.

Participants in both groups received usual inpatient rehabilitation care from a multi-disciplinary team that was individualised to the needs of each participant. This consisted of regular sessions with professionals such as physiotherapists, occupational therapists, recreational therapists, psychologists, nurses, rehabilitation physicians, and social workers. Participants in both groups could receive any type of physical rehabilitation including motor training directed at muscles and function below the level of the injury, but participants and sites were carefully instructed not to change usual care in response to the trial. The amount of time attending physiotherapy and occupational therapy as well as time actively exercising and training as part of usual care was captured for both groups using the International Spinal Cord Injury Physical Therapy-Occupational Therapy Basic Data Set (ISCI PT-OT BDS).[23] The details of therapy provided as part of the additional motor training to the Intervention group were captured in the same way.

Outcomes

Outcome data were collected at baseline before randomisation (except participants' impressions of therapeutic benefit), and then 10 weeks (±2 weeks) and 6 months (±1 month) after randomisation by independent blinded assessors. The baseline and 10-week assessments were conducted face-to-face by assessors employed at each site and were recorded in paper format. All assessors were trained online either individually or in small groups. Data were double-entered onto the REDCap database to guard against data entry errors. The 6-month assessments were conducted by telephone and the data were directly entered onto the REDCap database at the time of assessment. Logic checks were run across all baseline and outcome data before locking the database on July 31 2025.

The primary outcome was Total Motor Score of the International Standards for the Neurological Classification of SCI (0–100 points) at 10 weeks.[21] This outcome was used to reflect neurological recovery. There were 11 secondary outcomes measured at 10 weeks, or 6 months, or both. They were: upper extremity motor score (10 weeks); lower extremity motor score (10 weeks); total sensory score (10 weeks); American Spinal Injuries Association Impairment Scale (10 weeks); the Spinal Cord Independence Measure Version III–Self Report (SCIM-III SR; 10 weeks and 6 months); the Walking Index for Spinal Cord Injuries Version II (WISCI-II; 10 weeks and 6 months); WHO Quality of Life–BREF (WHOQOL-BREF; 10 weeks and 6 months); the European Quality of Life 5 Dimensions 5 Level questionnaire (EQ-5D-5L; 10 weeks and 6 months); participants' perceptions about ability to perform short-term and long-term self-selected goals (10 weeks and 6 months); participants' impressions of therapeutic benefit (10 weeks and 6 months); and time from randomisation to discharge (6 months; appendix pp 2–3). Detailed economic and process evaluation data were collected alongside the trial and will be reported separately.

The sponsor of the trial was the University of Sydney, Sydney, NSW, Australia but the trial was managed by George Clinical, an independent international Clinical Research Organisation. Experienced and independent trial monitors from George Clinical, the Oslo University Hospital, Oslo, Norway, and the Fondazione Santa Lucia Centre, Roma, Italy, conducted monitoring visits at each site to ensure compliance with the trial protocol and with the International Council for Harmonisation Guideline for Good Clinical Practice (ICH-GCP, E6(R2)). Serious adverse events were recorded during the 10-week intervention period by trial staff. Trial staff documented any complications reported directly by participants or identified through review of medical records. Serious adverse events were defined as those resulting in death, life-threatening conditions, prolongation of hospitalisation, or significant disability. The causality was independently arbitrated by a medically qualified investigator (IDC) who was unaware of treatment allocation.

Statistical analysis

A sample size of 220 was needed to provide a 90% power of detecting a between-group difference of 6 points on the Total Motor Score (0–100 points) 10 weeks after randomisation. The decision to use 6 points was based on the recommendations of the Committee representing The International Campaign for Cures of Spinal Cord Injury Paralysis.[25] This decision was subsequently endorsed and proven to be reasonable in a study specifically designed to determine the opinions of people with SCI and clinicians about the smallest worthwhile effect of motor training on the primary outcome using a benefit-harm trade-off approach.[26] The power calculations assumed a SD of the change in Total Motor Score of 13·3 points,[25] a worst-case loss to follow-up in both groups of 10%, and an α value of 0·0492 to allow for one interim analysis using the O'Brien–Fleming stopping rule.

A detailed statistical plan was made available before completion of the trial.[27] The data were analysed by statisticians from the George Institute for Global Health (including two authors [QL and JM], and overseen by Laurent Billot) using SAS Enterprise Guide version 7.1 (SAS/Stat version 9.4). The trial statisticians initially

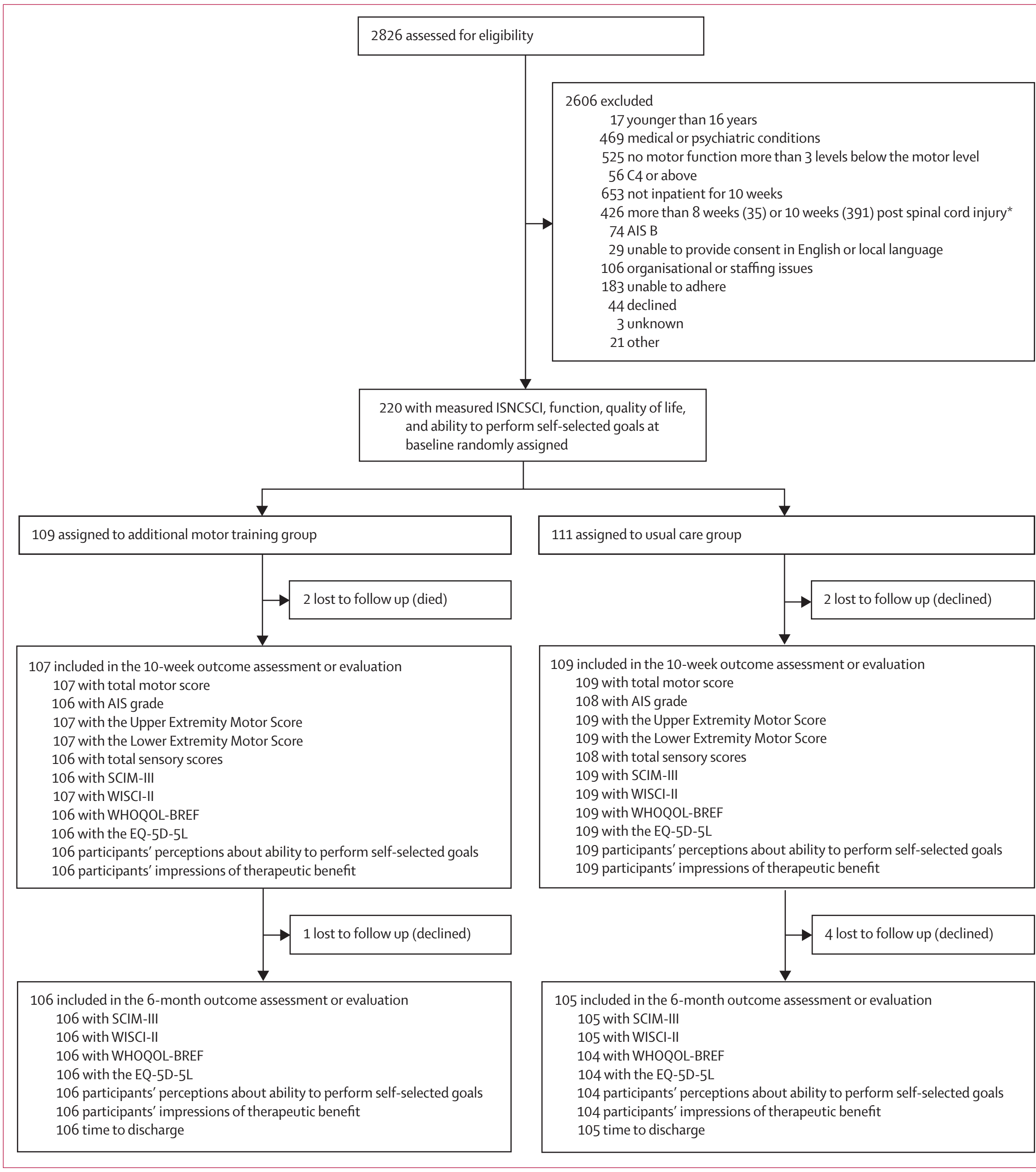

Figure 1: **Trial profile**
All numbers refer to the intention-to-treat population which was used for both safety and efficacy analyses. AIS=American Spinal Injuries Association Impairment Scale. ISNCSCI=International Standards for the Neurological Classification of SCI. SCIM-III=Spinal Cord Independence Measure Version III-Self Report. WISCI-II=Walking Index for Spinal Cord Injuries Version II. WHOQOL-BREF=WHO Quality of Life–BREF. EQ-5D-5L=the European Quality of Life 5 Dimensions 5 Level questionnaire. *The inclusion criterion was changed from 8 weeks to 10 weeks (appendix p 7).

conducted and validated the analyses using randomly shuffled group allocations.

All data were analysed on an intention to treat basis. An adjusted mean between-group difference in Total Motor Scores at 10 weeks, along with its 95% CI was estimated with a mixed linear regression model in which Total Motor Score at 10 weeks was regressed on group and baseline motor score. The model included the two stratification variables as covariates: level of injury (tetraplegia *vs* paraplegia) as a fixed effect and site as a random intercept. Other continuous outcomes were analysed using the same statistical model except when outcomes were measured at both 10 weeks and 6 months. For these outcomes, categorical time and the time by group interactions were added to the model, as were random intercepts for participants nested within sites. Participants' impression of therapeutic benefit was not measured at baseline; baseline Total Motor Score was used in its place as a baseline covariate.

An adjusted hazards ratio and 95% CI were estimated for the effect of the intervention on time to discharge with a Cox model that included baseline Total Motor Score and the two stratification variables, after confirming that the proportional hazards assumption was met. Participants were censored at 6 months or when they were last known to be in hospital, whichever occurred first. An adjusted odds ratio and 95% CI were estimated for the effect of the intervention on AIS grade (five grades) at 10 weeks using an ordinal logistic regression model that included baseline AIS grade and the stratification variables, after confirming that the proportional odds assumption was met. The odds ratio corresponded to the odds of shifting to a worse AIS grade. The appendix (p 4) details how missing data and non-adherence were dealt with.

A pre-planned subgroup analysis examined whether the effect of intervention was moderated by the level of the injury (tetraplegia *vs* paraplegia) or AIS Grade (AIS A *vs* AIS C or D). The subgroup analysis was only conducted on the primary outcome and used the same statistical model as used in the primary analysis except for the addition of the moderator variable and its interactions with group and time.

An independent Data Monitoring Committee oversaw unblinded outcomes and adverse event data according to a written charter and conducted a formal interim analysis when the first 117 participants had completed the 10-week assessment. The trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12621000091808; universal trial number: U1111-1264-1689) on Feb 1, 2021, before randomisation of the first participant.

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

The first and last participants were randomly assigned on June 7, 2021, and Feb 5, 2025, respectively, and the last participant completed the trial on July 22, 2025. 2826 individuals were admitted to the 15 hospitals within 3 months of injury and screened for inclusion, of whom 2606 were either ineligible or declined to participate (figure 1). Ultimately, 220 participants were randomly assigned to the control (n=111) or intervention (n=109) groups.

Four participants were lost to follow-up before the 10-week assessment (two participants from the control group withdrew without giving a reason, and two participants from the intervention group died). An additional two participants (one in each group) completed the primary outcome but declined to complete some of the other assessments at 10 weeks (figure 1). Consequently, the primary outcome was available at 10 weeks for 216 (98%) of 220 participants and the secondary outcomes for 214–216 of 220 participants. Outcomes at 6 months were available for 211 of 220 participants (one participant completed some but not all assessments). The 10-week and 6-month assessments were taken at a median of 10·1 (IQR 9·6 to 10·7) weeks and 6·1 (5·9 to 6·4) months after randomisation, respectively. Assessors confirmed that they were unintentionally unblinded for eight of the 10-week assessments and seven of the 6-month assessments (assessors' blinding status was unknown for one 10-week assessment and one 6-month assessment). An unplanned post-hoc sensitivity analysis for the primary outcome indicated a trivial effect opposite to what would be expected from the eight instances of assessor unblinding (appendix p 4).

	Intervention group (n=107)			Control group (n=109)
	Additional motor training	Usual care	Additional motor training and usual care	Usual care
Number of sessions per week	5·7 (5·1–7·8)	8·5 (6·2–10·5)	14·4 (12·0–18·6)	9·4 (6·6–11·8)
Hours scheduled to attend therapy per week	12·0 (11·3–12·0)	9·3 (6·2–12·0)	20·4 (18·0–23·6)	9·5 (7·2–14·0)
Hours attending therapy per week	11·0 (9·8–11·9)	7·8 (5·8–10·8)	18·4 (16·3–21·3)	8·4 (6·5–12·5)
Hours actively exercising in therapy per week	8·4 (6·6–9·6)	5·3 (3·9–7·2)	13·6 (11·4–15·5)	6·2 (4·5–8·3)
Hours scheduled to attend therapy in total	113·5 (100·5–120·5)	90·2 (65·2–114·8)	198·9 (174·1–229·8)	91·8 (71·0–128·0)
Hours attending therapy in total	105·8 (89·8–113·2)	76·1 (58·4–98·0)	177·7 (159·2–202·6)	83·0 (64·6–116·0)
Hours actively exercising in therapy in total	78·1 (63·3–90·4)	52·2 (38·9–68·3)	124·6 (107·3–142·3)	61·1 (44·2–80·0)

Data are median (IQR). Hours of therapy refers to the time spent in physiotherapy and occupational therapy sessions. The hours actively exercising refers to the time captured using the ISCI PT-OT BDS (time in physiotherapy and occupational therapy provided as part of usual inpatient rehabilitation is also devoted to other types of therapies and activities not captured with the ISCI PT-OT BDS). The data of four participants are not included because the participants dropped out before the 10-week assessment (two participants from the intervention group died, and two participants from the control group withdrew their consent). ISCI PT-OT BDS=International SCI Physical Therapy–Occupational Therapy Basic Data Set.

Table 1: **Amount of additional motor training provided to participants in the intervention group, and the amount of physiotherapy and occupational therapy provided as part of usual inpatient rehabilitation to all participants**

Participants in the intervention group were scheduled to attend a median of 12·0 h per week (IQR 11·3–12·0) but attended 11·0 h per week (9·8–11·9) of additional motor training (table 1). Missed sessions were due to a variety of reasons, particularly illness. Participants in the intervention group attended a total of 105·8 h (89·8–113·2) of additional motor training and 76·1 h (58·4–98·0) of physiotherapy and occupational therapy as part of their usual care over the 10-week intervention period, which together equated to a total of 177·7 h (159·2–202·6). In contrast, participants in the control group attended a total of 83·0 h (64·6–116·0) of physiotherapy and occupational therapy provided as part of usual care (appendix pp 5, 8).

The two groups were similar at baseline with respect to key prognostic factors such as age, time since injury, gender, and neurological status (table 2). 146 (66%) had a traumatic SCI and 74 (34%) had a non-traumatic injury (table 2).

	Intervention (n=109)	Control (n=111)	Total (n=220)
Age, years			
Mean (SD)	55·2 (17·3)	52·1 (14·8)	53·6 (16·1)
Median (IQR)	59·0 (43·0–68·2)	54·2 (42·4–63·7)	56·7 (42·9–67·2)
Time since injury, months*			
Mean (SD)	1·6 (1·2)	1·5 (0·5)	1·5 (0·9)
Median (IQR)	1·4 (1·2–1·8)	1·5 (1·0–1·9)	1·5 (1·1–1·9)
Gender			
Male	81 (74%)	88 (79%)	169 (77%)
Female	28 (26%)	23 (21%)	51 (23%)
AIS grade			
A	4 (4%)	8 (7%)	12 (5%)†
B‡	0	1 (1%)	1 (1%)
C	40 (37%)	35 (32%)	75 (34%)
D	65 (60%)	67 (60%)	132 (60%)
Cause of injury			
Traumatic	71 (65%)	75 (68%)	146 (66%)
Non-traumatic	38 (35%)	36 (32%)	74 (34%)
Level of injury			
Tetraplegic	68 (62%)	66 (59%)	134 (61%)
Paraplegic	41 (38%)	45 (41%)	86 (39%)
Time since first sat out of bed, days			
Mean (SD)	31·1 (16·1)	32·0 (16·7)	31·6 (16·4)
Median (IQR)	32·0 (21·0–43·0)	31·0 (18·0–48·0)	31·5 (20·0–45·0)
Neurological level of injury			
C1 to C4	46 (42%)	48 (43%)	94 (43%)
C5 to C8	21 (19%)	17 (15%)	38 (17%)
T1 to T7	16 (15%)	14 (13%)	30 (14%)
T8 to T12	16 (15%)	17 (15%)	33 (15%)
L1 to L5	10 (9%)	15 (14%)	25 (11%)
S1 to S5	0	0	0

Data are presented as mean (SD) and median (IQR), or n (%). Gender was self-reported by participants and they were given the option of using any term of their choosing. Data on race or ethnicity were not collected, analysed, or reported because these variables were not deemed to influence the way a person with SCI would respond to the intervention. AIS=American Spinal Injury Association Impairment Scale. *Time between date of injury and date of baseline assessment. †Four participants had tetraplegia and eight participants had paraplegia. ‡One participant was incorrectly classified as AIS B and included in the trial. It was decided before unblinding to include this participant in the analysis because the misclassification arose for a technical and controversial reason, and many clinicians would classify this type of injury as AIS C. Percentages might not sum to 100% due to rounding.

Table 2: **Baseline characteristics of participants**

The mean Total Motor Score at 10 weeks (the primary outcome) was 78·76 (SD 17·34) for the control group and 78·36 (SD 17·00) for the intervention group. The mean between-group difference on the primary outcome was 0·93 (95% CI –1·63 to 3·48; p=0·48; table 3).

The results of the secondary outcomes are reported in table 3 and the appendix (p 9). In brief, there were no discernible between-group differences in any of the secondary outcomes at either 10 weeks or 6 months except for the psychological domain of the WHOQOL-BREF (0–100 points) at 10 weeks which had a mean between-group difference of 4·97 (95% CI 0·64–9·29).

There were four serious adverse events including two deaths in participants from the intervention group (appendix p 10). Three of the serious adverse events were not related to the intervention including one death in the context of bilateral pneumonia, progressing to respiratory and cardiac failure. The fourth serious adverse event was the death of a participant in the intervention group. This participant developed a haematoma in one leg in the days preceding the participant's unexplained death. The haematoma was deemed to be possibly related to the intervention but it was not clear if the haematoma was related to the death.

In a pre-specified subgroup analysis, there was no evidence of effect moderation by level of injury (tetraplegia *vs* paraplegia; p=0·09) or AIS grade (AIS A *vs* AIS C or D; p=0·77) on the primary outcome (figure 2). Additional post-hoc exploratory subgroup analyses were conducted to explore possible evidence of effect moderation by type of injury (traumatic or non-traumatic), age, initial strength, and site. There was no indication of effect moderation by any of these variables (appendix p 6).

Discussion

This study shows that, when given in addition to the physiotherapy and occupational therapy provided as part of usual care in this trial, intensive task-specific training supplemented with strength training for 10 weeks has no statistically significant nor clinically meaningful effect on neurological recovery in individuals with recent SCI.

The design and conduct of the trial minimised but did not completely eliminate potential for bias. There was a high fidelity with the trial protocol and very little loss to follow-up. Trial participants and clinical staff were aware of allocation, but the primary outcome was assessed by blinded assessors and it is unlikely that participants' knowledge of allocation could have influenced the primary outcome. The greatest potential source of residual bias is likely to be differential co-intervention—ie, participants in one group received more usual care, or more effective usual care, than the other group. Data on the amount of physiotherapy and occupational therapy

	Baseline		Week 10		Effect at 10 weeks (mean between-group difference [95% CI])	6 months		Effect at 6 months (mean between-group difference [95% CI])
	Intervention group	Control group	Intervention group	Control group		Intervention group	Control group	
Total Motor Score (0–100)	63·84 (18·06; n=109)	66·23 (18·24; n=111)	78·36 (17·00; n=107)	78·76 (17·34; n=109)	0·93 (–1·63 to 3·48) p=0·48			
AIS grade (n=109 intervention, n=111 control at baseline; n=106 intervention, n=108 control at week 10)								
A	4 (4%)	8 (7%)	2 (2%)	4 (4%)	Proportional OR* 1·49 (0·67 to 3·27)	..	..	..
B	0	1 (1%)	1 (1%)	1 (1%)	..	..	..	..
C	40 (37%)	35 (32%)	21 (20%)	18 (17%)	..	..	..	..
D	65 (60%)	67 (60%)	82 (77%)	84 (78%)	..	..	..	..
E	0	0	0	1 (1%)	..	..	..	..
Upper Extremity Motor Score (0–50)	37·32 (12·94; n=109)	38·05 (12·69; n=111)	42·78 (9·31; n=107)	42·36 (9·36; n=109)	0·62 (–0·44 to 1·68)	..	..	..
Lower Extremity Motor Score (0–50)	26·52 (14·10; n=109)	28·18 (14·47; n=111)	35·59 (13·64; n=107)	36·40 (13·57; n=109)	0·30 (–1·70 to 2·30)	..	..	..
Total Sensory Score (0–224)	156·96 (39·92; n=109)	154·41 (42·89; n=111)	170·01 (40·44; n=106)	164·30 (41·49; n=108)	3·45 (–2·18 to 9·09)	..	..	..
SCIM-III SR (0–100)	32·43 (15·02; n=109))	36·30 (16·30; n=111)	56·10 (19·23; n=106)	57·68 (20·00; n=109)	0·98 (–3·18 to 5·13)	61·42 (19·81; n=106)	64·19 (19·02; n=105)	0·30 (–3·87 to 4·47)
WISCI-II (0–20)	2·36 (4·68; n=109)	3·68 (5·81; n=111)	10·94 (7·63; n=107)	11·75 (7·82; n=109)	–0·09 (–1·89 to 1·71)	13·94 (7·38; n=106)	14·68 (6·88; n=105)	0·01 (–1·80 to 1·82)
WHOQOL BREF (0–100)								
Domain 1: physical health	53·46 (15·96; n=109)	51·05 (17·15; n=111)	64·00 (16·52; n=106)	59·54 (17·67; n=109)	3·64 (–0·58 to 7·85)	60·93 (17·08; n=106)	60·55 (17·27; n=104)	–0·31 (–4·57 to 3·95)
Domain 2: psychological health	64·40 (19·31; n=109)	62·74 (20·51; n=111)	71·75 (17·98; n=106)	65·85 (20·75; n=109)	4·97 (0·64 to 9·29)	65·08 (20·36; n=106)	65·47 (18·60; n=104)	–0·73 (–5·10 to 3·63)
Domain 3: social relationships	64·73 (16·95; n=109)	64·31 (15·10; n=111)	69·09 (17·40; n=106)	65·26 (18·29; n=109)	3·74 (–0·73 to 8·22)	67·16 (18·63; n=106)	62·70 (18·79; n=104)	4·32 (–0·19 to 8·83)
Domain 4: environment	70·62 (14·28; n=109)	70·90 (15·62; n=111)	74·66 (14·91; n=106)	72·51 (16·54; n=109))	2·73 (–1·16 to 6·61)	71·21 (17·89; n=106)	69·97 (18·53; n=104)	1·91 (–2·02 to 5·83)
EQ-5D-5L index score (<0·000 to 1·000)	0·27 (0·19; n=109)	0·28 (0·23; n=111)	0·57 (0·29; n=106)	0·55 (0·33; n=109)	0·03 (–0·04 to 0·10)	0·62 (0·30; n=106)	0·63 (0·28; n=104)	0·00 (–0·07 to 0·07)
Perceived ability to perform self-selected goals for 10 weeks (0–10)	0·88 (1·23; n=109)	1·02 (1·39; n=111)	7·60 (3·00; n=106)	7·22 (2·87; n=109)	0·40 (–0·37 to 1·17)	7·67 (3·11; n=106)	7·79 (2·51; n=104)	0·00 (–0·77 to0·77)
Perceived ability to perform self-selected goals for 6 months (0–10)	0·24 (0·87; n=109)	0·30 (0·94; n=111)	3·99 (3·25; n=106)	4·21 (3·21; n=109)	–0·21 (–1·10 to 0·67)	5·27 (3·69; n=106)	5·85 (3·27; n=104)	–0·53 (–1·42 to 0·36)
Participants' impressions of therapeutic benefit (–7 to 7)	..	..	5·48 (1·33; n=106)	5·17 (1·53; n=108)	0·40 (–0·11 to 0·91)	5·04 (2·23; n=106)	4·63 (2·50; n=104)	0·47 (–0·04 to 0·99)
Days from randomisation to hospital discharge	..	..	..	..	..	115·01 (63·09; n=106)	116·31 (85·20; n=105)	HR† 1·10 (0·81 to1·48)

Data are mean (SD) and n (%). The effects are difference in means with 95% CIs estimated from the model. AIS=American Spinal Injury Association Impairment Scale. SCIM-III: Spinal Cord Independence Measure Version III - Self Report. WISCI-II=Walking Index for Spinal Cord Injuries Version II. WHOQOL-BREF=WHO Quality of Life–BREF. EQ-5D-5L=the European Quality of Life 5 dimensions 5 levels questionnaire. HR=hazard ratio. *The effect of the intervention was estimated as the odds ratio corresponding to the odds of shifting to a worse grade category. †The effect of the intervention was estimated as adjusted HR where a HR of more than 1 indicates that the additional motor training decreased the time to discharge. Percentages might not sum to 100% due to rounding.

Table 3: **Primary and secondary outcomes and estimates of effect**

provided as part of usual care show that the control group received slightly more physiotherapy and occupational therapy as part of usual care than those in the intervention group even though the hours of scheduled therapy were the same for both groups. The discrepancy between scheduled and delivered therapy arose because participants in the intervention group declined some therapy sessions offered as part of usual care, probably because they had received the maximum amount of therapy they could tolerate. The imbalance in hours spent in usual care being small, the associated co-intervention bias would also be expected to be small.

	Mean (SD)		Mean difference (95% CI)	$p_{interaction}$
	Intervention	Control		
AIS grade				0·77
A	55·50 (27·49)	63·13 (25·81)	–1·09 (–12·42 to 10·24)	
C and D	79·25 (16·02)	80·05 (16·10)	0·62 (–1·97 to 3·20)	
Level of injury				0·09
Tetraplegia	76·77 (18·72)	75·22 (18·76)	2·72 (–0·55 to 5·99)	
Paraplegia	80·93 (13·61)	83·80 (13·78)	–1·80 (–5·84 to 2·23)	

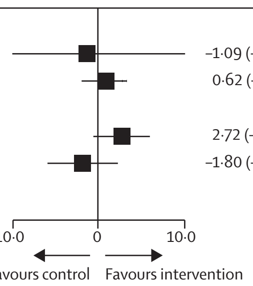

Figure 2: **Forest plot of subgroup analysis for the Total Motor Score of the International Standards for the Neurological Classification of SCI**
AIS=American Spinal Injuries Association Impairment Scale. SCI=Spinal Cord Injury.

The findings should not be generalised to settings which provide less usual care than was provided in the trial. However, the amount of physiotherapy and occupational therapy provided as part of usual care by the sites in this trial reflect current practices in five high-income countries and 15 hospitals that provide SCI rehabilitation, and is similar to the amount of physiotherapy and occupational therapy usually reported in the literature.[28–30]

It is possible that the absence of effect of intensive motor training was due to features of the trial. Specifically, the absence of effect might have arisen because the inclusion criteria or outcome measures were inappropriate or 12 h per week of additional motor training over 10 weeks was insufficient. We consider each of these possibilities in turn.

The trial's inclusion criteria were intended to select individuals most likely to respond to the trial intervention. We screened 2826 individuals with recent SCI to recruit 220 participants based on strict eligibility criteria. Thus, the trial population is a carefully selected group. Any further tightening of the eligibility criteria would only further reduce the generalisability of the trial's findings. The pre-planned subgroup analysis did not identify subgroups defined by the level of injury or AIS grade in which intensive motor training was more effective.

It is possible that the additional motor training would have been more effective if it was administered in a larger dose, for example, if the additional motor training was provided for more than 10 weeks or more than 12 h per week. However, the possibility of extending the duration of motor training beyond 10 weeks in the inpatient environment is becoming increasingly unattainable because lengths of inpatient stays are getting shorter (median length of stay in the USA is now 42 days).[30] Furthermore, patients with SCI might not be medically stable or ready to participate in a physically demanding rehabilitation programme until several weeks after injury, so the window for participation in an inpatient rehabilitation programme can be quite narrow. Sustainable provision of intensive therapy for patients with SCI post discharge from hospital is challenging,[31] although it is possible that intensive therapy could be provided over a long period of time to individuals with SCI on an outpatient basis with the appropriate financial support and if they lived close to service providers. The possibility of providing more than 12 h per week of additional motor training during the inpatient stay could also be difficult to implement without shortening other therapies and activities provided as part of inpatient rehabilitation. It was difficult, in this trial, to fit an additional 12 h of motor training into the participants' busy inpatient rehabilitation programmes.

The primary outcome was Total Motor Score. This provides a measure of neurological recovery and is a surrogate endpoint for function because the extent of weakness and paralysis largely determines a person's ability to move. The absence of a beneficial effect of motor training on the primary outcome was supported by similar findings in other functional secondary outcomes. It is possible that the intervention could have produced detectable effects on different surrogate measures of neurological status. However, it is probable such changes would not be meaningful to individuals with SCI. Meaningful outcomes for individuals with SCI include an improvement in the ability to walk, as assessed by the WISCI-II, or the ability to move and live independently, as assessed by the SCIM-III SR, which were not significantly different between both groups at 10 weeks. It is also possible that measures such as the SCIM-III SR are insensitive to change particularly in certain subgroups of participants. However, if this had been the case, we would expect to see an indication of treatment effect on patient-reported outcomes such as Perceived Ability to Perform Self-selected Goals and Participants' Impressions of Therapeutic Benefit, which was note evident.

There was a significant effect of the intervention on the psychological domain of the WHOQOL-BREF although the size of the effect was small. This could be a false positive finding caused by testing multiple secondary outcomes. It is also possible that, because this outcome was self-reported, it was more vulnerable to reporting bias than others. A third possibility is that there was, in fact, a psychological benefit provided by intensive motor training. The effect is consistent with preliminary findings from the process evaluation conducted alongside the trial (not yet published). In interviews conducted as part of the process evaluation, many participants expressed the belief that they needed as much therapy as possible, particularly therapy that was directed at the weak or paralysed muscles below the level of injury, and particularly therapy directed at regaining the ability to walk. The additional motor training might have addressed this need and explained the effect on the psychological domain of the WHOQOL-BREF. However, we believe that similar effects could be attained by educating therapists, researchers, and the media about the harms of ableist attitudes that promote walking at all costs, and which instil the belief in individuals with SCI that those who work hard during therapy can defy the odds.[32]

It is interesting to consider why the findings from animal studies on activity-dependent spinal plasticity and neurological recovery did not translate in a simple way to clinical practice. It might be that individuals with SCI are already receiving an optimal dose of task-specific training as part of usual care, rendering additional therapy redundant, or it might be that animal models of spinal plasticity do not generalise well to humans with SCI.

The findings of this trial have important implications for clinicians and administrators responsible for providing SCI rehabilitation services. We found no evidence to support the need for additional motor training beyond what was provided as part of usual care in this trial. Individuals who have experienced a recent SCI can be reassured that the usual amount of motor training they currently receive is sufficient and that any residual disability is not due to a failure to train hard enough.

Contributors

LAH, JVG, and IDC conceptualised the trial. LAH, JVG, IDC, CS, HL, SJ, SS, GW, DT, JK, SP, VJ, CL, and GS secured funding. JVG, GS, JS, JC, MB, KET, CR, SR, FT, CL, FDN, LWC, DR, VJ, JL, CCML-G, MM, EJG, SP, CB, KO, and LVR managed the sites. GS, JS, CR, SR, FT, CL, FDN, LWC, DR, VJ, JL, CCML-G, MM, EJG, SP, CB, and LVR provided training to trial staff. LAH, JVG, and JC curated the data. JVG, MB, KET, and JC oversaw the delivery of the intervention. LAH, JVG, and JC managed the trial and administrative duties. QL, JM, RDH, and LAH developed the statistical plan and conducted the analyses. LAH, JVG, JC, QL, and IDC interpretated the results. LAH, JVG, and JC wrote the first draft of the manuscript. All authors had an opportunity to provide input to, and contribute to, the interpretation of the results and to critically revise and edit the manuscript and approve the final manuscript. LAH, QL, and JM directly accessed and verified the underlying data reported in the manuscript. All authors had full access to the data if desired and had final responsibility for the decision to submit for publication.

Declaration of interests

LAH's position is funded by the State Insurance Regulatory Authority, and icare. EM reports grant support from Wings for Life, Stoke Mandeville Spinal Research Fund and consulting fee from Liberate Medical. All other authors declare no competing interests.

Data sharing

Data are available upon reasonable request. Deidentified participant data underlying main results may be provided to researchers who provide LAH (l.harvey@usyd.edu.au) with a methodological proposal. Approval for data access will be granted on a case-by-case basis at the discretion of the principal investigator. The data will be accessible from the date of this article's publication and will be available for a period of 5 years thereafter.

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