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ORIGINAL RESEARCH

Was the Motor Training in the SCI-MT Trial Delivered by Therapists and Received by Participants According to the Protocol? A Fidelity Analysis

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Abstract

Objectives: To determine whether the motor training provided to people with spinal cord injury (SCI) in the "Early and Intensive Motor Training for people with Spinal Cord Injuries (SCI-MT) Trial" was delivered by therapists and received by participants according to the protocol. Intervention delivery and intervention receipt correspond to 2 fidelity domains of the National Institutes of Health Behavior Change Consortium framework.

Design: Observational and audit study.

Setting: Inpatient rehabilitation gymnasiums.

Participants: Therapists administering and participants (n=107) receiving the motor training within the SCI-MT trial.

Interventions: Not applicable.

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Main Outcome Measures: Indirect measures included audits of practice sheets (exercise training logs) and trial charts. Direct measures comprised 40 spot audits of treatment sessions using a checklist assessing adherence to the key principles of motor training.

Results: The protocol required therapists to provide 12 hours of intensive motor training per week for 10 weeks (120h total), and participants were expected to spend as much time as possible actively exercising during sessions. The trial chart audit showed the participants attended a median of 11.0 hours (interquartile range [IQR], 9.8-11.9) per week, for a median of 10.0 weeks (IQR, 9.4-10.4), equivalent to a median of 105.8 hours (IQR, 89.8-113.2). The median adherence of therapists' delivery of motor training to the key principles assessed in spot audits was 100% (IQR, 87%-100%). Participants actively exercised for a median of 73.7 hours (IQR, 63.0-91.3) over the 10-week trial period.

Conclusions: The motor training provided as part of the SCI-MT Trial was largely delivered by therapists and received by participants as intended. These findings strengthen confidence in the fidelity of the intervention and will support interpretation of the trial's outcomes.

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A recently completed multicenter pragmatic randomized controlled trial, the "Early and Intensive Motor Training for people with Spinal Cord Injuries: The SCI-MT Trial," found that 10 weeks of intensive motor training, administered in addition to usual inpatient rehabilitation, did not improve neurologic recovery or function in people with recent spinal cord injury (SCI).[1] The trial involved 220 participants, recruited from 15 sites across Australia and Europe. Although the motor training was individualized, it followed some key principles. Specifically, it had to involve high repetitions of active purposeful movements, target muscles innervated below the level of injury, progress over the 10 weeks, and be performed at high intensity. Other key principles included weekly goal setting, use of augmented feedback and exercise targets, and use of practice sheets (i.e., exercise training logs). A detailed description of the intervention, including the key principles of motor training, can be found elsewhere.[2]

As part of the trial, and before any analysis of outcomes, we prospectively collected data to evaluate the fidelity of the SCI-MT Trial intervention. Our evaluation was informed by the National Institutes of Health Behavior Change Consortium (NIH BCC) framework,[3,4] which categorizes fidelity into 5 domains: study design, therapist training, intervention delivery, intervention receipt, and intervention enactment. Consistent with recommendations for complex rehabilitation interventions,[5] our fidelity evaluation focused on the intervention delivery and intervention receipt domains.

Intervention delivery refers to the extent to which therapists administered motor training as specified in the trial protocol. It has 2 components: the dose and quality of motor training delivered.[3,4,6] The protocol required therapists to provide 12 hours of motor training per week for 10 weeks.[7] Because participants did not always attend all scheduled sessions, we distinguished between the time scheduled and the time participants attended. Importantly, this dose does not refer to the time participants spent actively exercising (fig 1). The quality of motor training delivered reflects how well the principles of motor training were adhered to. In contrast, intervention receipt reflects the time participants attended motor training, and how much of that time they spent actively exercising (figs 1 and 2). Participants were not expected to practice or enact the intervention outside their training sessions; therefore, the enactment domain was not evaluated.

The importance of monitoring and evaluating fidelity in complex interventions has been well established.[5,8,9] High intervention fidelity can strengthen a trial's internal and external validity[4,5,10] and help explain trial results. In negative trials without fidelity measures, it is difficult to determine whether the intervention was truly ineffective or whether key components were not delivered as intended, potentially leading to false negative conclusions. This can lead to the discarding of a potentially effective intervention. Similarly, in positive trials, fidelity data help clarify whether the observed effects can be attributed to the full intervention or only specific components.[10]

Despite these benefits, intervention fidelity is not often evaluated and is poorly reported in trials investigating exercise-based and rehabilitation interventions, with a few exceptions.[9,11-14] This gap is particularly evident in trials involving people with SCI, where only limited aspects of intervention fidelity are typically reported, and often only briefly, within the primary publication. Fidelity evaluation is especially important in SCI trials investigating rehabilitation interventions because they are inherently complex, involving individuals with diverse neurologic impairments, goals, and needs. The SCI-MT intervention presented additional challenges because of the large number of therapists across multiple sites and countries. These factors highlighted the need for a rigorous evaluation of how consistently the intervention was delivered across the sites. Evaluating fidelity before knowing the trial results increases transparency and guards against bias, ensuring that the interpretation of fidelity data is not influenced by the outcomes of the trial.[13]

In line with the therapist training NIH BCC domain, considerable efforts were made to ensure consistent delivery of the SCI-MT intervention across sites.[3,8] A comprehensive training package was developed, including a 2-3-hour online training session and an intervention manual. The online training was delivered "live" by teleconference (Zoom) by one of the principal investigators and the research team. Staff unable to attend "live" training sessions viewed a recording instead. Regardless of format, all therapists met online with a principal investigator after completing the training to address questions and reinforce key principles (see supplemental table S1, available online only at http://www.archives-pmr.org/ for details about the amount of training provided).

List of abbreviations:

IQR	**interquartile range**
NIH BCC	**National Institutes of Health Behavior Change Consortium**
SCI	**spinal cord injury**
SCI-MT	**Early and Intensive Motor Training for People with Spinal Cord Injury**

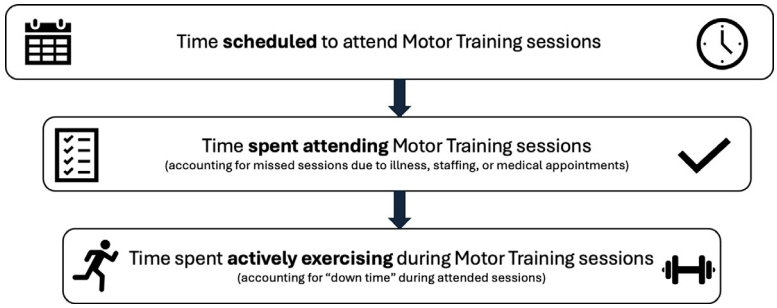

Fig 1 The 3 aspects of the motor training dose that were evaluated with the trial chart and practice sheet audits.

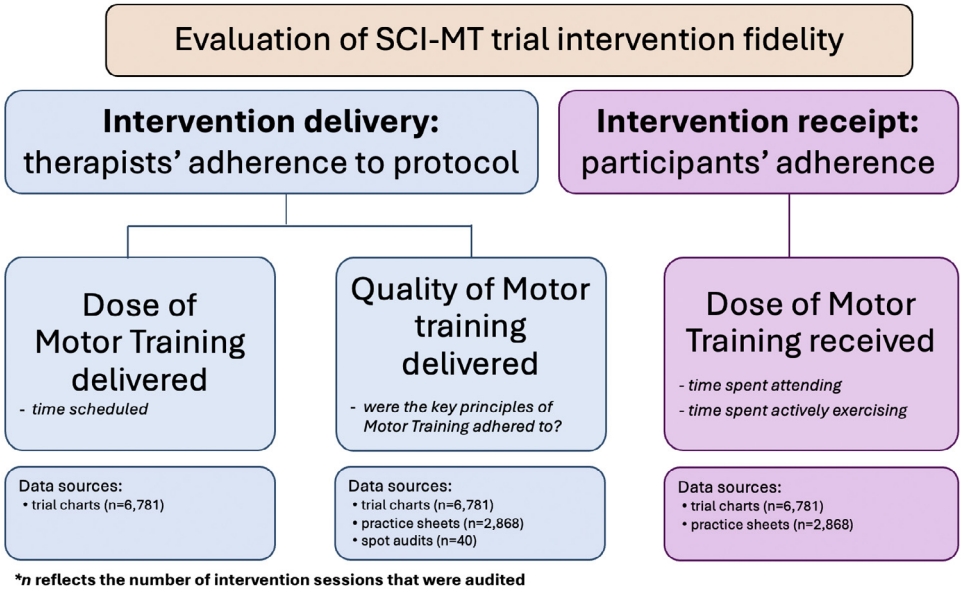

Fig 2 Evaluation of SCI-MT trial intervention fidelity, measuring the intervention delivery and intervention receipt domains of the NIH BCC framework.

The training package detailed the key principles of the SCI-MT intervention and included examples of task-specific training and strength training exercises, 4 hypothetical case studies illustrating how to use the practice sheets. The practice sheets were integral to the intervention and were used to record exercise set-up, repetitions, and time spent actively performing each exercise, essential for setting and progressing exercise targets. Therapists were taught how to use the practice sheets and to involve participants when reviewing exercise parameters and setting exercise targets. The practice sheets were also used to document and review weekly goals. Together, these strategies were intended to encourage participants to work at a high intensity and to progressively increase the difficulty of each training session.

Despite the efforts of all the staff, therapists, and participants involved in the SCI-MT trial, it cannot be assumed that the intervention was delivered or received exactly as intended. Drawing on the NIH BCC framework (fig 2), this study sought to evaluate intervention delivery and intervention receipt in the following ways:

Intervention delivery

The dose of motor training delivered: the amount of time scheduled to attend the motor training sessions.

Quality of motor training delivered: how well the motor training was delivered according to its key principles, including the time allocated to different types of exercises and training strategies.

Intervention receipt

The dose of motor training received: the amount of time participants spent attending the motor training sessions and the amount of time they spent actively exercising during these sessions (dose received), reflecting the extent to which participants received the intervention as intended.

Therefore, this study aimed to provide a rigorous evaluation of intervention delivery and intervention receipt to determine the fidelity with which the SCI-MT intervention was implemented.

Methods

A total of 109 participants were randomly assigned to the intervention group, however, 2 participants died before the 10-week assessment (unrelated to participation in the trial). Therefore, data are reported for 107 intervention participants. Guided by the NIH BCC framework, data sources from indirect and direct measures were used to evaluate intervention delivery and intervention receipt (fig 2). Indirect measures included audits of the trial charts and practice sheets, whereas direct measures included spot audits of intervention sessions. Trial chart audits were used to determine the amount of time intervention participants were scheduled to attend, attended, and spent actively exercising during the motor training sessions. Audits of practice

sheets were used to evaluate therapists' adherence to the key principles of motor training and to capture the amount of time the participants spent actively exercising during intervention sessions. Spot audits were used to further evaluate adherence to the key principles of motor training during intervention delivery. Detailed methods for the data-collection processes are provided in supplemental appendix S1 (available online only at http://www.archives-pmr.org/).

Data extraction and analysis

All data were stored on a secure REDCap database.[a] Results were analyzed descriptively with counts, means (SD), or medians (interquartile range [IQR]) using Stata (version 16).[b]

Results

The results are presented according to the NIH BCC fidelity framework, with findings categorized as reflective of either intervention delivery or intervention receipt (fig 2).

Audit of trial charts

The results from the trial chart audit reflected all aspects of intervention delivery and receipt (fig 2). The trial charts of 107 intervention participants were audited, reflecting 6781 motor training sessions. The participants attended a median of 11.0 hours (IQR, 9.8-11.9) of motor training per week or 105.8 hours (IQR, 89.8-113.2) in total, although they were scheduled to attend a median of 12.0 hours (IQR, 11.3-12.0) per week or 113.5 hours (IQR, 100.5-120.5) in total. The motor training was delivered over a median of 10.0 weeks (IQR, 9.4-10.4) by physiotherapists, occupational therapists, or exercise physiologists (table 1). The amount of time spent on the 5 activity-directed interventions (i.e., task-specific training) and 2 impairment-directed (i.e., strength and endurance training) of the International Spinal Cord Injury Physical Therapy and Occupational Therapy Basic Data Set is shown in table 1.

Audit of practice sheets

The results from the practice sheet audit provided measures of intervention delivery (i.e., quality of motor training delivered) and receipt (i.e., time spent actively exercising) (fig 2). Practice sheets from 60 intervention participants were audited, with one practice sheet for every week of training, capturing all sessions for a participant (practice sheets were not used for 2% of sessions). In total, 600 practice sheets were audited, reflecting 2868 motor training sessions. The audits revealed that participants actively exercised for a median of 73.7 hours (IQR, 63.0-91.3) over the 10-week trial period. At least 1 weekly goal was set, with an average of 3 goals (2-3) set per week. A median of 100% (IQR, 100%-100%) of audited exercises targeted muscles innervated below the level of injury. Importantly, there was strong evidence of exercise progression, with 90% of reviewed practice sheets scoring 2 (ie, strong evidence) for this criterion. Additional details about adherence to key principles from the practice sheet audit are listed in table 2.

Spot audits

The results from the spot audits were used to reflect the quality of motor training delivered (fig 2). Forty spot audits were completed involving 22 participants and 29 intervention therapists from 10 (of 15) sites. Five sites were not audited because of language barriers. A total of 250 exercises were observed across all audits. The median duration of audited sessions was 90 minutes (IQR, 60-98), with a median of 6 exercises (IQR, 5-8) per session (see table S2). All observed motor training sessions were delivered one-to-one in a therapy area by a qualified therapist as dictated by the study protocol. The demographics of the intervention therapists and of participants observed during spot audits are provided in supplemental tables S3 and S4 (available online only at http://www.archives-pmr.org/).

The spot audits revealed a high-quality intervention delivery, adhering to most of the key principles of motor training according to the trial protocol. The median fidelity score reflecting the quality of delivery across all observed sessions was 100% (IQR, 87%-100%). The therapists showed the highest levels of adherence to the following key principles: exercise administered in high dosages (high repetitions and intensity), use of goal-oriented instructions, and use of practice sheets for exercise set-up (table 3). Use of augmented feedback (particularly knowledge of performance feedback) and use of exercise targets were the least adhered to aspects of motor training.

Discussion

Our fidelity evaluation showed that therapists delivered a high dose of motor training, with the participants attending a median of 11.0 hours (IQR, 9.8-11.9) per week of motor training, although they were scheduled to attend a median of 12.0 hours (IQR, 11.3-12.0). The discrepancy between the scheduled and attended time reflected issues common to rehabilitation settings, including participant illness, medical appointments, COVID-19-related restrictions, and staffing-related challenges, and did not indicate systematic deviations from the protocol. The trial chart and practice sheet audits showed that the participants spent a median of 8.4 hours (IQR, 6.6-9.6) actively exercising while attending motor training sessions (table 1). The discrepancy between attendance and active exercise largely reflected "downtime," including training-related discussion (eg, provision of instructions or feedback), exercise set-up, and rest. Rest was particularly important during the early weeks of the intervention, when participants were more likely to experience fatigue while exercising at high intensities. These downtime periods were also observed during spot audits and were consistent with practice sheet data.

Practice sheets were at the core of the SCI-MT Trial and were used to support implementation of the key principles of the intervention. It was thus important to establish that the therapists used the practice sheets as intended. Therapists used practice sheets for exercise set-up and recording in 89% of sessions evaluated during spot audits (table 3). Adherence to this component of the intervention was encouraged by the research team, who regularly reviewed the practice sheets and provided support to the intervention therapists over the course of the trial. The support was in the form of refreshers regarding the purpose of practice sheets through regular newsletters, meetings, and informal one-to-one feedback sessions.

The practice sheet audit demonstrated consistent setting of weekly goals and progression of exercises over the 10-week trial period. However, goals were only specific and measurable 86% of the time (IQR, 73%-100%) (table 2), although setting specific and measurable goals is considered integral for effective motor training.[15,16] Challenges associated with goal setting for people

Table 1 Audits of trial charts (n=107)[†]: details of motor training sessions scheduled for and subsequently attended by participants of the intervention group.

	Scheduled	Attended
Total time over 10 wk (h)	113.5 (100.5-120.5)	105.8 (89.8-113.2)
Total time per week (h)	12.0 (11.3-12.0)	11.0 (9.8-11.9)
Total number of sessions over 10 wk	62.0 (53.0-81.0)	57.0 (51.0-76.0)
Total number of sessions per wk	8 (6-10)	6 (5-8)
Total number of weeks of additional motor training	NA	10,0 (9.4-10.4); 9.6 (1.0)
Total number of sessions missed over 10 wk	3.0 (1.0-7.0)	NA
Proportion (%) of sessions scheduled/provided by different professionals		
Physiotherapists	100 (89-100)	100 (90-100)
Occupational therapists	0 (0-6)	0 (0-6)
Other	0 (0-0)	0 (0-0)
No discipline specified	0 (0-0)	0 (0-0)
Total time spent on activities categorized according to ISCI PT-OT BDS (h)		
Bed/seated control activities	NA	4.6 (1.8-16.7); 11.9 (16.2)
Standing control activities	NA	11.3 (5.2-19.2); 12.9 (9.3)
Walking, stairs	NA	8.8 (0.7-19.0); 11.7 (12.8)
Gross motor upper extremity	NA	0.8 (0.0-2.4); 3.3 (7.6)
Fine motor upper extremity	NA	1.4 (0.0-6.4); 4.3 (5.8)
Strength training	NA	26.4 (12.0-38.7); 26.7 (18.0)
Endurance training	NA	2.3 (0.8-6.6); 4.0 (4.6)
Total time spent on activities and impairments		78.1 (63.3-90.4); 74.9 (21.3)
Total, per wk		8.4 (6.6-9.6); 7.9 (2.3)
Proportion (%) of time spent on activities categorized according to ISCI PT-OT BDS[‡]		
Bed/seated control activities	NA	7 (2-22); 17 (21)
Standing control activities	NA	16 (8-23); 17 (11)
Walking, stairs	NA	13 (1-23); 14 (14)
Gross motor upper extremity	NA	1 (0-4); 4 (9)
Fine motor upper extremity	NA	2 (0-9); 6 (7)
Strength training	NA	35 (20-51); 37 (23)
Endurance training	NA	3 (1-10); 6 (7)

NOTE. All data are presented as median (IQR). The means (SD) are also provided for "total number of weeks of additional motor trainig", all "total time spent on activities and impairments", and "proportion (%) of time spent on activities categorized according to ISCI PT-OT BDS) data".
Abbreviation: ISCI PT-OT BDS, International Spinal Cord Injury Physical Therapy and Occupational Therapy Basic Data Set
[†] A total of 109 participants were initially randomly assigned to the intervention group. Two participants died before the 10-week assessment.
[‡] Proportions were calculated for each individual before deriving the median (IQR) and mean (SD). Unlike mean proportions, median proportions are not additive and therefore do not sum to 100%, reflecting the skewed distribution of the data.

with early SCI have been well documented,[17] so some inconsistencies among the therapists are not unexpected. Although goal setting in the SCI-MT Trial was not perfect, it represents only one aspect of the broader intervention. Therefore, the less-than-perfect goal setting alone is unlikely to account for the negative SCI-MT Trial results. Nevertheless, given the inherent complexity of goal setting, the SCI-MT intervention would have been further optimized by providing more structure and greater emphasis on this aspect during therapist training.

Spot audits revealed strong evidence of therapists' use of goal-oriented instructions during delivery of the motor training (table 3). Goal-oriented instructions involve setting exercise goals and targets, supported by clear explanations, with or without demonstrations by the therapists to the participants.[18] Exercise goals inform the person about what they are trying to achieve, typically in relation to variables that indicate successful exercise performance (eg, distance, speed, load, repetition, or time). In contrast, exercise targets are closely related to exercise goals but are used to guide the person on where they should move to. For example, markers on the floor can be used as targets to indicate the desired foot placement during stepping practice; an object on a table can be used to indicate how far the person should reach; and a bar set to a specified height can be used as a target indicating how high the knee should be raised during hip flexion exercises in standing. Together, exercise goals, targets, and clear instructions and demonstrations from therapists inform the participants about what is required and how to successfully complete an exercise. They also encourage participants to work at a high intensity.[19] The intervention therapists demonstrated consistent adherence to setting exercise goals and providing clear instructions, although the use of exercise targets was less evident (table 3).

The key motor training principle that was least adhered to was the use of augmented feedback, particularly knowledge of performance feedback (table 3). This may reflect insufficient attention provided to this specific component of motor training during the training of trial staff. Nonetheless, this is an important aspect of effective teaching of motor tasks,[18,20,21] which is often inadequately incorporated into the therapy provided by physiotherapists.[22]

The trial protocol dictated that task-specific training be prioritized over strength training where possible. The audit of the trial charts revealed that participants spent 54% of therapy time on task-specific training and 36% of therapy time on strength training (see

Table 2 Audits of practice sheets (n=60)*: adherence to key principles of additional motor training by the intervention therapists (that could not be evaluated with spot audits).

	Median (IQR)
Time spent on actively engaging in exercise	
Total time over 10 wk (h)	73.7 (63.0-91.3)
Total time per wk (h)	8.1 (6.3-9.1)
Proportion (%) of sessions in which practice sheets were used	98
Number of goals set per wk†	2.8 (1.9-3.3)
Proportion (%) of weeks with ≥1 goal	100
Proportion (%) of goals that were	
Specific and measurable†	86 (73-100)
Required active contractions of muscles below the level of injury†	100 (100-100)
Proportion (%) of exercises that required active contractions of muscles below the level of injury†	100 (100-100)
Evidence that exercises were progressed over the intervention period, (0-2 points)‡	2.0 (2.0-2.0)
Evidence that exercises addressed the weekly goals, (0-2 points)‡	2.0 (1.8-2.0)

* Practice sheets were missing for 1 participant in week 1 and for a different participant in week 2.
† The scores for each item within a practice sheet audit were averaged and then used to attain a median (IQR) across all practice sheet audits.
‡ Evidence was scored on a 3-point scale (0=no evidence, 1=some evidence, and 2=strong evidence). The scores within each practice sheet were averaged and then used to attain a median (IQR) from these values.

Table 3 Spot audits (n=40): adherence to key principles of additional motor training by the intervention therapists (that could not be evaluated with practice sheet audits).

	n=40	
Key Principle of Motor Training	Median (IQR)*	Proportion of the 250 observed e xercises that attained a m aximal score of 2 Points (%)
1. Delivered exercise at appropriate dosage (i.e., number of repetitions)	2.0 (1.8-2.0)	88
2. Delivered exercise at high intensity	2.0 (1.7-2.0)	86
3. Provided KP feedback	1.3 (0.5-1.7)	49
4. Provided KR feedback	1.7 (1.4-2.0)	80
5. Set-up exercise targets	1.2 (0.6-2.0)	56
6. Provided exercise goals	1.8 (1.2-2.0)	72
7. Gave clear instructions and/or demonstrations	2.0 (2.0-2.0)	95
8. Referred to the practice sheets when setting up an exercise	2.0 (2.0-2.0)	90
9. Recorded the details of an exercise in the practice sheet	2.0 (2.0-2.0)	88

NOTE. Evidence was scored on a 3-point scale (0=no evidence, 1=some evidence, and 2=strong evidence).
Abbreviations: KP, knowledge of performance; KR, knowledge of results.
* The scores for each exercise within a spot audit were averaged and then used to attain a median (IQR) across all spot audits.

table 1 for details and an explanation about time not totaling to 100%). Anecdotally, participants with extensive paralysis tended to spend more time on strength training than task-specific training, and vice versa. Therapists prioritized strength training for people with very limited muscle strength (i.e., grade 1 or 2) because whole-task practice was difficult to administer effectively and safely. Although body weight support treadmill training, upper and lower limb robotics, and functional electrical stimulation can facilitate task-specific training for very weak participants,[23-27] the availability of these types of equipment varied across sites, and even when available, they were used infrequently. For example, 10 participants out of the 60 included in the practice sheet audits were from the 2 sites that had access to lower limb robotics yet only 3 participants used this equipment (all recruited from the same site), spending a total of 53 hours (of 872 hours) on Lokomat training. Similarly, upper limb robotics was used with 4 participants across 2 sites for a total of 32 hours, even though 17 participants with tetraplegia were recruited from the 6 sites with access to this equipment. Functional electrical stimulation cycles (upper or lower limb) were used with 12 participants for a total of 49 hours across 11 sites, and body weight-supported treadmill training was used for 7 participants for a total of 20 hours. Body weight support systems (with or without the use of walking aids) were used for overground gait training, standing balance, sit-to-stand, and stepping training a lot more frequently than they were used with treadmill training at most of the sites. The reasons for limited use of robotics and other advanced assistive technologies were not explored, but commonly reported barriers include substantial set-up and doffing time, the need for extensive training and technical troubleshooting skills, and therapists' general lack of confidence with the use of these types of devices.[28,29] It is likely that the SCI-MT therapists experienced similar challenges, and their use of equipment was consistent with real-world practice. Consequently, most exercises involved part-task or whole-task practice using common types of simple equipment that were easily available in the therapy gyms. This was the case for all participants.

Although we captured how motor training was delivered and the amount of training participants received, we did not measure factors such as participants' willingness to engage in the training or therapists' willingness to provide it. Nor did we assess how confident either group felt or their levels of fatigue; these aspects were explored qualitatively through participant and therapist interviews reported in a separate publication.[30] These factors may have influenced how actively participants engaged with motor training and, in turn, the quality of the therapy they received. This is particularly relevant in those with recent SCI, where readiness to engage, fatigue, and other psychological factors can vary widely. These sources of variation are inherent to real-world clinical practice, and the SCI-MT Trial was designed to test the effectiveness of the intervention under these pragmatic conditions. Nonetheless, future trials that better capture these aspects of behavioral engagement would provide a more complete understanding of how the intervention was delivered and received. Conducting even simple fidelity studies alongside clinical trials requires substantial resources, including careful planning, therapist training, ongoing monitoring, and detailed data auditing and analysis. Researchers need to be confident that such an investment is warranted and should prioritize capturing these data in trials such as the SCI-MT Trial, which are likely to have important implications for clinical practice.

Study limitations

There were some limitations to this study. Specifically, spot audits were completed by one rather than 2 independent raters, and interrater reliability was not assessed. In addition, the rater completing the audits was involved in the trial, introducing the potential for bias. The use of independent raters and formal evaluation of the interrater reliability would have strengthened the study's methodological rigor. However, having the same rater complete all audits ensured consistency across the spot audits at the different sites. In addition, the therapists were aware that they were being observed, which may have influenced intervention delivery during spot audits. Nonetheless, direct observations are considered the criterion standard for evaluating fidelity.[31] Although therapists demonstrated good understanding and ability to implement the intervention according to the trial protocol when audited, it is unknown whether the same high standard was maintained when not observed. Another limitation relates to the practice sheet audit, where 60 of the 107 participants were selected to provide a representative estimate of fidelity; however, auditing all participants would have strengthened the evaluation. In addition, the 2- and 3-point rating scales used in the audit were relatively crude measures of fidelity. A 5- or 10-point scale may have provided greater sensitivity.

Conclusions

The fidelity evaluation completed in parallel to the SCI-MT Trial supported the interpretation of trial results and strengthened its internal and external validity.[9,32] Guided by the NIH BCC framework, we evaluated the fidelity of the SCI-MT Trial intervention using indirect and direct measures collected before knowing trial outcomes. Consistent with recommendations for complex interventions,[5,33] a combination of different data sources was used to provide a comprehensive evaluation of intervention fidelity. The findings indicate that the therapists delivered the motor training in high dosages, adhering to its key principles and trial protocol, and participants received a high dose of training. Overall, these findings suggest that poor intervention fidelity is unlikely to explain the absence of a treatment effect in the SCI-MT trial.

Suppliers

a. REDCap; Vanderbilt University.
b. Stata, version 16; StataCorp.

Keywords

Adherence; Exercise therapy; Rehabilitation; Spinal cord injuries

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Data statements

Deidentified data are available from the authors upon reasonable request and with approval from the principal investigator. Requests must be accompanied by a methodologically appropriate proposal.

Ethics statement

Ethical approvals were provided by relevant committees (Northern Sydney Local Health District, number 2020/ETH02540), and written informed consent was obtained from all the participants and the therapists who were observed during the spot audits.

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