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Early and Intensive Motor Training for people with spinal cord injuries (the SCI-MT Trial): protocol of the process evaluation

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ABSTRACT

Introduction People with spinal cord injury receive physical rehabilitation to promote neurological recovery. Physical rehabilitation commences as soon as possible when a person is medically stable. One key component of physical rehabilitation is motor training. There is initial evidence to suggest that motor training can enhance neurological recovery if it is provided soon after injury and in a high dosage. The Early and Intensive Motor Training Trial is a pragmatic randomised controlled trial to determine whether 10 weeks of intensive motor training enhances neurological recovery for people with spinal cord injury. This pragmatic randomised controlled trial will recruit 220 participants from 15 spinal injury units in Australia, Scotland, Italy, Norway, England, Belgium and the Netherlands. This protocol paper describes the process evaluation that will run alongside the Early and Intensive Motor Training Trial. This process evaluation will help to explain the trial results and explore the potential facilitators and barriers to the possible future rollout of the trial intervention.

Methods and analysis The UK Medical Research Council process evaluation framework and the Implementation Research Logic Model will be used to explain the trial outcomes and inform future implementation. Key components of the context, implementation and mechanism of impact, as well as the essential elements of the intervention and outcomes, will be identified and analysed. Qualitative and quantitative data will be collected and triangulated with the results of the Early and Intensive Motor Training Trial to strengthen the findings of this process evaluation.

Ethics and dissemination Ethical approval for the Early and Intensive Motor Training Trial and process evaluation has been obtained from the Human Research Ethics Committee at the Northern Sydney Local Health District (New South Wales) in Australia (project identifier: 2020/ETH02540). All participants are required to provide written consent after being informed about the trial and the process evaluation. The results of this process evaluation will be published in peer-reviewed journals.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This protocol provides the detailed methodology of a process evaluation designed to explain the results of one of the largest physiotherapy trials yet conducted in spinal cord injury.
⇒ The protocol provides a detailed template for process evaluations of similar trials.
⇒ It is difficult to predict how COVID-19 may influence our ability to complete all planned aspects of the process evaluation.

Trial registration number Australian New Zealand Clinical Trial Registry (ACTRN12621000091808); Universal Trial Number (U1111-1264-1689).

INTRODUCTION

Spinal cord injury (SCI) can result in profound paralysis and weakness that limit a person's ability to move. This impacts on individuals' physical well-being, independence and quality of life. Therefore, a key aim of physical rehabilitation following SCI is to promote neurological recovery so as to reduce the extent of weakness and optimise a person's ability to move. Physical rehabilitation typically commences as soon as possible after injury and once a person is medically stable.[1–4] It has many components, but one component of physical rehabilitation is motor training. Motor training is a form of therapy that includes task-specific training and strength training. The key components of task-specific training are goal setting, feedback and progression, along with repetitious practice of purposeful movement.[5–7] The aim is to restore movement to as near that of a

person's pre-injury function as possible. The key components of strength training are progressive resistance training for stronger muscles and repetitious contractions for weaker muscles. Both aspects of motor training (ie, task-specific training and strength training) can involve the use of robotics, electrical stimulation and treadmill training with overhead support, but these interventions alone do not define motor training, rather they are tools to help provide it. The motor training provided as part of the Early and Intensive Motor Training for SCI trial (the SCI-MT Trial) is intensive and specifically directed at the neurologically weak muscles at and below the level of injury.

Motor training has been shown to drive neuroplasticity in animal models and studies involving people with stroke and other neurological conditions.[8–17] A recent systematic review looked at the effectiveness of any type of motor training below the level of injury in people with SCI on neurological recovery (defined as a change in strength in muscles directly affected by the SCI).[18] Twenty-six randomised controlled trials were included in this systematic review. These randomised controlled trials provided motor training in various ways and dosages. Together they provided initial evidence that motor training increases strength and promotes neurological recovery in people with SCI. Further, they suggest that the effects of motor training can be enhanced if provided soon after injury in high dosages. However, this is yet to be proven. Hence, the aim of the SCI-MT Trial is to determine the effect of early and intensive motor training on neurological recovery (as determined by the total motor score of the International Standards for Neurological Classification of SCI (ISNCSCI)) and function in people with recent SCI. Both groups continue to receive usual care that includes limited motor training in addition to many other types of therapies (eg, prescription of equipment, home modifications, wheelchair skills training and treatment of contractures and pain).

This process evaluation will run alongside the SCI-MT Trial. Process evaluations are important for complex trials such as the SCI-MT Trial. They combine qualitative and quantitative data from different sources to help explain the trial results and identify potential facilitators and barriers to the future rollout of the intervention in different contexts and settings if found to be effective.[19–22] To explain the trial results, it is important to determine the trial fidelity and to ascertain whether the intervention was delivered as intended in terms of the dosage and quality of the intensive motor training.[19 23] This information can also be used to explore some of the assumptions underpinning the trial as to why the intervention was believed to be sufficiently promising to test (as outlined in figure 1). For example, we will use the data from the process evaluation to test assumption #2: intensive motor training needs to be commenced soon after injury; and assumption #3: motor training needs to be provided at a high dosage. It helps identify for whom, how and why the trial intervention was or was not effective, and ways to adapt the intervention to fit different clinical contexts. Process evaluations are also important for capturing the perspectives of participants, therapists and relevant stakeholders through interviews. Their perspectives on the intervention and the trial can help improve the intervention and its implementation, explain the trial results and be used to identify potential facilitators and barriers to the future rollout of the intervention in various clinical settings/contexts if the intervention is found to be effective.[24 25] This is particularly relevant to policymakers and administrators tasked with implementing evidence-based effective interventions.

The aims therefore of this process evaluation are to:

1. Explain the SCI-MT Trial results by:
   - Exploring the reasons why the intensive motor training may or may not have been effective, and for whom, how and why.
   - Determining whether the intensive motor training was delivered as intended with respect to its fidelity and dose.
2. Explore the potential facilitators and barriers to the possible future rollout of the intensive motor training in different clinical contexts/settings if it is found to be effective.

METHODS AND ANALYSIS

Summary of SCI-MT Trial

The SCI-MT Trial is a multicentre pragmatic randomised controlled trial. The trial will recruit 220 participants from 15 sites across 7 countries in Australia and Europe. The trial has already commenced and was prospectively registered with the Australian New Zealand Clinical Trial Registry (ACTRN12621000091808). All participants receive usual rehabilitation (usual care) as provided in their SCI units. Usual care may include some motor training; however, participants randomised to the intervention group will also receive intensive motor training for 12 hours per week for 10 weeks on top of usual care. The intensive motor training is individualised to the needs of each participant and includes task-specific training and strength training directed at the neurologically weak muscles below the level of the lesion. It is delivered by therapists during face-to-face therapy sessions. The primary outcome is the total motor score of the ISNCSCI at 10 weeks. The secondary outcomes include measures of neurological status, function, ability to walk, quality of life and participants' perception of ability to perform self-selected goals and impressions of therapeutic benefit at 10 weeks and 6 months. The study protocol of the SCI-MT Trial is published elsewhere.[26] This paper is devoted to the protocol of the process evaluation of the SCI-MT Trial.

Theoretical frameworks for the process evaluation of the SCI-MT Trial

The SCI-MT Trial process evaluation is based on the UK Medical Research Council process evaluation framework

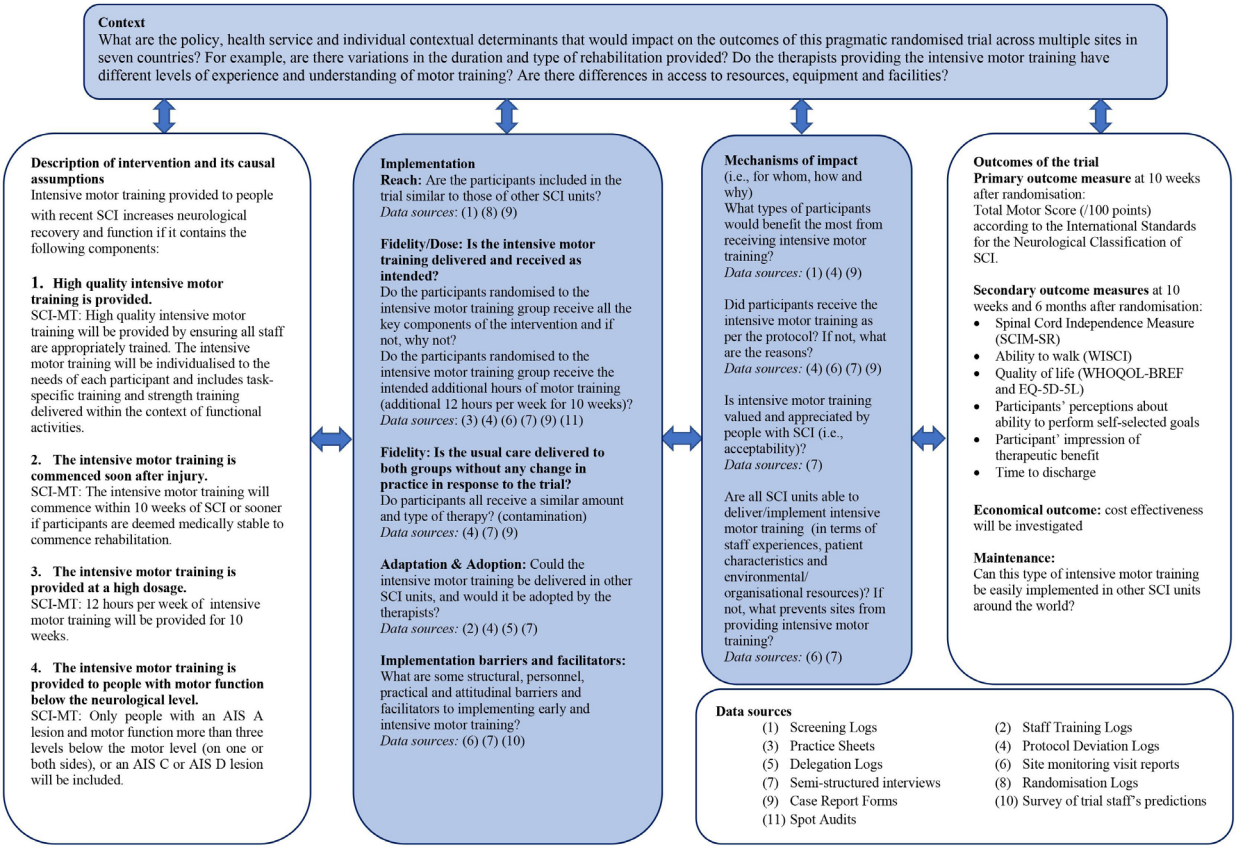

Figure 1 The SCI-MT Trial process evaluation framework is based on the UK Medical Research Council process evaluation framework. AIS, American Spinal Injury Association Impairment Scale; SCI, spinal cord injury; SCI-MT, Early and Intensive Motor Training; SCIM-SR, Spinal Cord Independence Measure- a self report version; WISCI, Walking Index for Spinal Cord Injury; WHOQOL- BREF, World Health Organisation Quality of Life-BREF; EQ-5D-5L, EQ-5D 5 level.

and the Implementation Research Logic Model (IRLM) as described below.

The UK Medical Research Council process evaluation framework

We will use this framework to articulate our key questions under the headings of (1) context, (2) implementation and (3) mechanism of impact (as outlined in the blue boxes of figure 1). The framework will enable us to communicate the relationship between these questions and the underlying assumptions as well as the outcomes of the trial (as outlined in the white boxes of figure 1). A summary is as follows:

Context

We will take into account the various contexts in which the intensive motor training is delivered throughout the process evaluation. For example, we will consider factors such as the staffing levels, as well as skills and expertise of the therapists at each site. We will also take into account access to resources, equipment and facilities, and the potential impact of COVID-19 across and within countries. These considerations will be important for explaining the trial results and could potentially guide the future rollout of the intervention.

Implementation

We will determine whether the intensive motor training was delivered as intended (fidelity) in terms of the dosage of treatment as well as the content of the therapy. It will be important to assess the fidelity of the intensive motor training provided to the intervention participants of the trial. Fidelity will be assessed by looking at data sources such as case report forms (CRFs) and practice sheets to ascertain if the intervention was delivered as intended.

Mechanism of impact

We will examine the underlying assumptions of the SCI-MT Trial and explore trial participants' expectations and acceptance of the early and intensive motor training to promote neurological and functional recovery for people with SCI. The findings from this may help us identify possible facilitators or barriers to future rollout. It will help guide recommendations about site-specific adaptations that may be needed if the intensive motor training is to be implemented in different clinical settings.

The Implementation Research Logic Model

The SCI-MT Trial process evaluation will also use the IRLM to iteratively examine the complex relationships between key components of the intervention, implementation

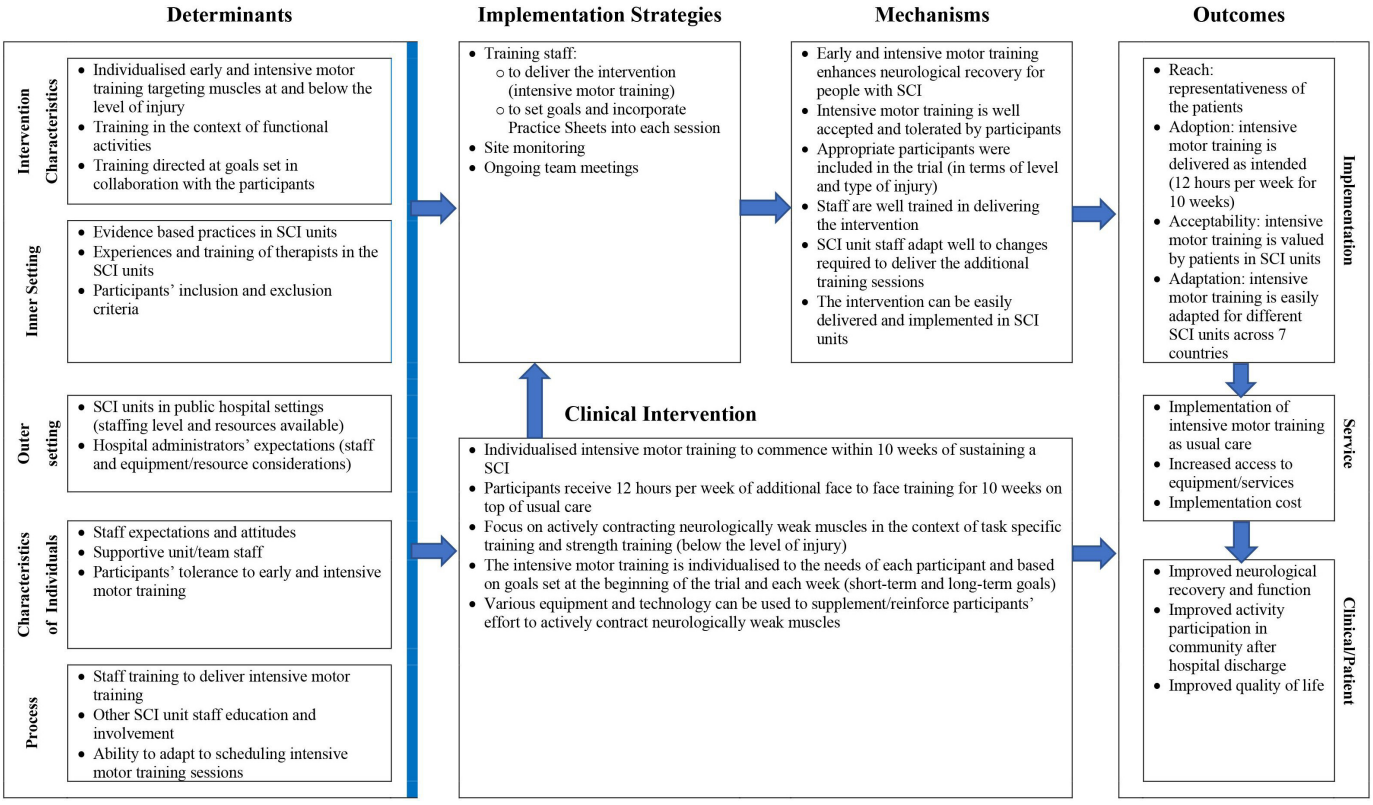

Figure 2 Implementation Research Logic Model for the SCI-MT Trial process evaluation. This model describes various determinants, implementation strategies, mechanisms and outcomes. SCI, spinal cord injury; SCI-MT, Early and Intensive Motor Training.

strategies and implementation outcomes.[27] The IRLM provides a visual depiction of key components of SCI-MT Trial that will help us explore the future reproducibility of the intensive motor training if it is to be implemented across various clinical settings (figure 2). It also provides a systematic and comprehensive way to integrate the results from the various data sources. This model will be used to present and interpret our findings, and to test whether the underlying causal assumptions are correct.

Data collection

Various qualitative and quantitative data will be collected to address the aims of SCI-MT process evaluation (see figure 1 for a list of the data sources). The following sections outline the different sources of data that will be collected as part of the process evaluation and the rationale for their inclusion.

Participant demographics

Demographics information including participants' age, gender, country of recruitment, severity of injury (tetraplegia vs paraplegia) and type of injury (as per the American Spinal Injury Association Impairment Scale) as well as the time since the participant's injury and since the participant first sat out of bed will be collected. These data will be recorded using the CRFs (data source 9; see figure 1), and to check that the intervention was administered to the target population, and to test assumption #2 (intensive motor training needs to be started soon after injury) and assumption #4 (intensive motor training is effective in people with partial paralysis below the neurological level) (see figure 1). These data will also be used to determine whether the participants are similar to those of other SCI units. The data will be tallied (online supplemental file 1: Table 1).

Trial participants', therapists' and stakeholders' perceptions of the trial and potential for future rollout of intensive motor training

Semi-structured interviews (data source 7; see figure 1) will be conducted to determine whether the trial was conducted as intended with the overarching aim of explaining the trial results. The interviews will also be used to provide insights into potential facilitators and barriers to the future rollout of the intensive motor training if found to be effective.

Twenty trial participants, 10 therapists and 10 stakeholders will be selected by purposive sampling and interviewed on a one-to-one basis. The trial participants will be sampled from the intervention and control groups ensuring a mix of severities of injuries (tetraplegia vs paraplegia), ages (<50 years of age vs ≥50 years of age) and sites. The 10 therapists will be selected from the involved recruitment sites. They may be therapists delivering the intensive motor training or usual care. The 10 stakeholders will include heads of departments from the recruitment sites/hospitals, representatives from SCI support networks, representative of professional

associations and academics involved in teaching physiotherapy students.

The interviews will follow a detailed interview guide (online supplemental file 1: interview guide) that has specific questions tailored to the background of the interviewees. It will probe issues that may hinder or assist the future rollout of the intervention including organisational structures, funding, staffing capacity and training. Some questions will explore participants' and therapists' perspectives of the intensive motor training that could influence the future rollout in different contexts. For example, participants who have received, and therapists who have delivered, the intensive motor training will be asked to reflect on the pros and cons of the intervention. In addition, participants in the intervention group and the therapists providing the intensive motor training will be asked questions to explore the trial fidelity and perceived mechanisms of impact of the intensive motor training. We anticipate that trial fidelity may be impacted by COVID-19 and will be raised by the interviewees.

The intensive motor training provided to the intervention participants

Details about the scheduled and delivered intensive motor training for the intervention participants will be captured through CRFs, practice sheets and spot audits (data sources 3, 9 and 11; see figure 1). These will be used to determine if the intensive motor training was delivered as intended and to provide insights into how the intensive motor training may be best rolled out in the future. The details are as follows:

Case report forms

Details about each scheduled and delivered intensive motor training session will be captured on a CRF based on the International Spinal Cord Injury Physical Therapy-Occupational Therapy Basic Data Set (V.1.2)[28] modified for the purposes of the trial (online supplemental file 1: intervention CRF). The data set was designed to capture physiotherapy and occupational therapy interventions that could conceivably increase the total motor scores that form part of the ISNCSCI or scores on the Spinal Cord Independence Measure or the Functional Independence Measure. Exercises and training provided as part of the intensive motor training will be categorised into one of five activity-related interventions or two impairment-related interventions. The CRF will be used to record the time and proportion of overall session time actively engaged in each of the seven interventions. In addition, the CRFs will capture all scheduled intensive motor training sessions, the overall amount of time spent in intensive motor training sessions (including time devoted to set-up, chat and rest) and the reasons for any missed sessions.

The data from the CRFs will be collated to reflect the following variables which will all be expressed as medians (IQR): number of scheduled intensive motor training sessions per participant per week, number of provided intensive motor training sessions per participant per week, time spent in each session of intensive motor training, time spent on each type of intervention provided as part of the intensive motor training, number of missed intensive motor training sessions per week, as well as the percentage of intensive motor training sessions delivered on each day of the week and at different times of the day (online supplemental file: Tables 2 and 3). These data will provide insights into the quantity of intensive motor training provided which will help determine whether the intervention was delivered as intended. This in turn will help explain the trial results.

Practice sheets

Details about the type and quantity of intensive motor training provided will also be captured on weekly practice sheets (online supplemental file 1: practice sheets). The practice sheets are an important component of the intervention. They will be used during each intensive motor training session to capture the weekly goals (between 1 and 4 goals are required) and the details of how each exercise is performed each day including descriptions/images of the exercises, repetitions and time spent doing the prescribed exercises. The exercises are prescribed by the treating therapist and individualised to the needs of each participant while following the key principles of motor training. The practice sheets function to increase motivation and adherence, ensure weekly goals are set, progress exercises, encourage counting of repetitions of exercises and encourage therapists to set targets for each exercise during each session based on prior performance. They will be completed by the treating therapists during each intensive motor training session.

The practice sheets will be audited to determine whether the intensive motor training was administered as intended. This will include determining whether practice sheets were created and used for every session. For this purpose, the proportion of sessions per participant in which practice sheets were used will be reported. The practice sheets will also be audited to determine the amount of time participants spent actively engaged in therapy (as opposed to the overall time they spent in a therapy session which includes time resting, chatting and setting up). The total amount of time spent actively engaging in some type of motor training (captured on the practice sheets) will be expressed as a percentage of the time participants spent in therapy (as captured on the CRFs; online supplemental file 1: Table 3).

The practice sheets of 60 participants will be audited. They will be randomly sampled from each site in proportion to the number of participants recruited at the sites. This will be 50% of all practice sheets: this is deemed an appropriate number to reflect the content of all practice sheets. Each practice sheet will be rated using audit forms specifically designed for the SCI-MT Trial. Two independent assessors with a background in physiotherapy and SCI will rate the selected practice sheets to determine how well the practice sheets adhere to four

Table 1 The four key attributes that will be used to audit the practice sheets to determine whether the intensive motor training was administered as intended

Attribute	Details
1. Were appropriate goals set for each week?	This will be determined in two ways: First, the practice sheets will be examined to determine the number of goals set per week. This will also be expressed as the median (IQR) proportion of weeks with at least one goal (expressed in relation to total number of weeks training) over the intervention period (online supplemental file: table 1). Second, each goal will be scored on a yes/no basis (0–not satisfied; 1–satisfied) for two criteria, namely: Criteria 1: is the goal specific and measurable, outlining what is to be achieved with respect to either assistance, aids and time (or similar), and could success be measured? Criteria 2: is the goal related to a motor activity that requires active contractions of muscles below the level of injury? The data will be expressed as the proportion of all goals for the 60 participants who satisfied each of these two attributes (online supplemental file: table 2).
2. Did the exercises involve active contraction of muscles below the level of the injury?	Each exercise recorded on the practice sheets will be scored on a 2-point scale where a score of 0 indicates that the exercise does not, and a score of 1 indicates that the exercise does, involve active contraction of muscles below the level of the injury. The scores will then be tallied for each participant to reflect the proportion of exercises per participant on the practice sheets that adhere to this principle. These scores will be expressed as a median (IQR) proportion for the 60 included participants (online supplimental file: table 1).
3. Was the training progressed?	The practice sheets of each participant will be scored on a 3-point scale where a score of 0 indicates no evidence that the exercises were progressed over the 10 weeks, a score of 1 indicates some evidence that the exercises were progressed and a score of 2 indicates strong evidence that the exercises were progressed. Evidence of progression includes increases in repetitions, resistance, duration or difficulty of an exercise. For example, moving from practising to standing up from a 65 cm high chair to a 60 cm high chair would be indicative of progression. These scores will be expressed as a median (IQR) for the 60 included participants (online supplemental file: table 2).
4. Did the exercises address participants' weekly goals?	The practice sheets of each week for each participant will be scored on a 3-point scale where a score of 0 indicates no evidence that any of the exercises addressed the participants' weekly goals and a score of 2 indicates strong evidence that the exercises addressed the participants' weekly goals. The scores for each week will then be tallied for each participant and divided by the number of weeks of training. These scores will be expressed as a median (IQR) for the 60 included participants (online supplemental file: table 2).

key attributes (see table 1 for the details of each of the four attributes).

Spot audits

The therapy sessions of participants from the intervention groups will be observed by a trained physiotherapist during spot audits either in person or via a secure teleconferencing platform. A checklist will be used to determine whether the key components of the intervention are delivered as per the protocol.[29] That is, the checklist will be used to capture and rate on a 3-point scale factors such as how well repetitious task-specific training and strength training are delivered; whether exercises are goal driven; whether therapy is delivered at a high intensity; whether exercise targets are set; and whether the therapist provides feedback.

Amount of training required by staff to deliver the intervention

All staff involved in delivering the intensive motor training will be trained. The amount of time spent in training and the type of training provided will be recorded on the staff training and delegation logs (data sources 2 and 5; see figure 1). These data will be tallied and used to check that staff were appropriately trained (an aspect of trial fidelity), and to gauge the amount of training that future staff would require if intensive motor training were to be rolled out and the implications of this on resource allocation and budgets (online supplemental file 1: Table 4).

The usual care provided to all participants

The type and dosage of therapy that forms part of usual care provided to all participants will be captured using the CRF (data source 9; see figure 1). These will be similar to those used to capture the intensive motor training (online supplemental file 1: intervention CRF) and will be used to record every scheduled and provided therapy session of usual care. The types of therapy sessions that will be captured include: individual or group sessions with physiotherapists, occupational therapists and exercise physiologists. The data will be collated and presented as outlined in Table 5 in the supplementary file (online supplemental file 1: Table 5).

Data on the type and dosage of usual care will be important for quantifying usual care at each recruitment site and determining whether there are any changes in usual care in response to the trial. For example, it is possible that in response to the trial, there may be an increase over time in the amount of motor training provided as part of usual care to all participants. These data will also help determine treatment contamination between intervention and usual care groups.[30 31] This would be evident by a selective increase in the amount of motor training provided to the control participants as part of usual care without a corresponding increase to the intervention participants. Contamination is a serious threat to the trial because it potentially reduces the

differences in therapies between the two groups. If this were to occur, it could lead to a negative trial finding.

Protocol deviations

The number and type of protocol deviations will be collated from the protocol deviation logs and site monitoring visit reports. The protocol deviation logs (data source 4; see figure 1) are kept by each site and cross-checked during site monitoring visits. The site monitoring visit reports (data source 6; see figure 1) are generated by independent auditors who regularly visit and monitor each site. Both the protocol deviation logs and site monitoring visit reports will be reviewed to capture any deviation from the protocol. Protocol deviations have been defined in the protocol. For example, it details acceptable time windows between the baseline assessment and: (1) randomisation, (2) the 10-week assessment and (3) the 6-month assessment. It also includes tolerance for variations on the amount of intensive motor training provided to intervention participants (online supplemental file 1: Table 6). In addition, chart audits of the CRFs (data source 9; see figure 1) will be used to determine protocol deviations due to failure to provide sufficient intensive motor training (a protocol deviation is defined as either less than 8 hours in any 1 week and/or less than 80 hours of intensive motor training over the course of the trial). These data will help ascertain whether the intensive motor training was delivered as intended and provide insights into the fidelity of the study intervention. Information about when and why intervention participants did not receive the intended amount of intensive motor training will also help explain the trial results (if the results are negative) and help identify the barriers and facilitators to the future rollout of the intensive motor training (if the results are positive).

Number of participants screened and reasons for exclusion

The screening and randomisation logs (data sources 1 and 8; see figure 1) at each site will be audited to determine the number of participants who were not suitable for the trial and the reasons. These data are important for checking that those who were potentially suitable were recruited: an aspect of trial fidelity. The data are also important for determining the generalisability of the trial results, and the implications for service providers if intensive motor training is to be rolled out in the future. For example, if only 1 in 40 participants admitted to an SCI unit were eligible, then the rollout of intensive motor training will be less burdensome for service providers than if 1 in 10 participants were eligible. However, a recruitment rate of 1 in 40 also suggests that intensive motor training will not have widespread implications because of the small number of people who will potentially benefit from it (online supplemental file 1: Table 7). The screening and randomisation logs will also be used to determine the effect of any barriers to recruitment including those related to public health issues. For example, sites will record when potential participants are unable to be recruited because of COVID-19.

Trial staff's predictions of the trial results

All staff involved in the trial (including therapists providing usual care and the intensive motor training, assessors, statisticians, site principal investigators and associate investigators) will be surveyed either within a year of the trial commencing or within a year of their involvement with the trial (data source 10; see figure 1). The surveys will be anonymous and designed to determine staff's expectations of the trial results. Specifically, they will be asked whether they think additional intensive motor training (as provided in the SCI-MT Trial) will:

- Increase total motor scores by, on average, at least 6 of 100 points (over and above any increase in motor scores that may occur with usual care).
- Have a clinically important effect on any of the secondary outcomes of the trial (over and above any effects that may occur with usual care). This includes measures of neurological status (except total motor score), ability to walk, function, quality of life, ability to achieve goals, perceived therapeutic effect or time to discharge.

Data will also be collected on staff's roles in the trial, their professional backgrounds, their SCI experience and their own rating of their knowledge about the existing evidence on the effectiveness of intensive motor training. The data will be summarised as counts and medians (IQRs) (online supplemental file 1: Table 8).

These data will help identify the risk of bias. Bias favouring the intervention is more likely to creep into trials in which all staff believe the intervention under investigation is effective than trials in which staff are undecided. Understanding potential sources of bias could help explain the trial results. These data will also help identify barriers and facilitators to the possible future rollout of the intervention. For example, if staff indicate that they expected the trial to demonstrate treatment effectiveness, this will suggest that staff have positive attitudes towards the intervention and vice versa.

Analyses

Qualitative analysis

Interviews will be recorded and transcribed verbatim. A subset of transcripts will be coded independently by three researchers. A coding frame will be developed and refined according to the emerging themes. These identified themes will be analysed within the process evaluation framework. We will use NVivo software[32] to manage the qualitative data. Five transcripts from the interviews will be coded together by JC, HL and LH (HL and LH have experience in qualitative research). Regular discussions will be carried out to identify any issues with the coding framework and analysis. Remaining transcripts will be divided and coded separately. Both deductive and inductive analyses will be used by analysing various data sources (list of data sources; see figure 1).

Quantitative analysis

Quantitative data will be presented descriptively using means (SD), medians (IQRs), percentages and counts as appropriate (online supplemental file 1: Table shells). All statistical analyses will be performed using Stata Statistical Software V.16.[33] All quantitative and qualitative data will be analysed iteratively before the final analysis of the SCI-MT Trial results as per UK Medical Research Council Guidance.[19] The qualitative and quantitative data will be together used to address the key questions of the process evaluation related to implementation and mechanisms of impact (see figure 1). These findings will then be triangulated with the final results of the SCI-MT Trial primary outcome to explore trial fidelity, and the reasons why the intensive motor training may or may not have been effective and for whom, how and why.

Patient and public involvement

The SCI-MT Trial, and its embedded process evaluation, was designed after consulting key stakeholders. We directly consulted the clinical teams from participating SCI units and their patients to define the question and intervention. A person with SCI is an investigator and another person with SCI is a consumer representative who sits on our Steering Committee. In addition, a key aspect of this process evaluation are the interviews. These will capture the experiences and perspectives of people with SCI and all relevant stakeholders.

Ethics and dissemination

Ethical approval has been obtained from the ethics committees representing the Northern Sydney Local Health District (for the Australia sites, 2020/ETH02540), Fondazione Santa Lucia IRCCS (for the Italian site; Prot. CE/PROG.928), Medical Ethics Committee of Maxima Medical Centre, Veldhoven (for the Adelante site and De Hoogstraat Rehabilitation Site in the Netherlands: CCMO code: NL78377.015.21), Central Committee on Medical Research Involving Human Subjects, Norway (for the Norwegian site, 278129), Yorkshire and the Humber–Bradford Leeds Research Ethics Committee (for the UK sites: 21/YH/0306) and Ethische Commissie Onderzoek UZ/KULeuven (for the Belgium sites: S65931). All participants are required to provide written consent after being informed about the trial and the process evaluation. They are provided with a participant information sheet.

Findings of the process evaluation will be published in peer-reviewed journals and presented at conferences. We are planning three publications to cover different aspects of the process evaluation. The first and second publications will be completed prior to the completion of the trial: one will be devoted to the findings from the interviews and the other will look at the fidelity of the SCI-MT Trial intervention. The third publication will not be completed until the trial results are known. It will be devoted to explaining the trial results and exploring the potential facilitators and barriers to implementing the intervention in various clinical contexts if it is found to be effective. These three publications will complement each other and ensure all data are fully reported and explored. They will be an important contribution to the field because process evaluations are not commonly conducted alongside clinical trials in the field of neurological rehabilitation,[34] yet they are needed to understand complex interventions tested in trials and to ensure the future successful rollout of interventions found to be effective.

Trial status

The first participant was randomised on 7th July 2021 and 134 participants have been recruited as of August 2023.

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