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Experiences and perceptions of participants, therapists and stakeholders about the intervention provided as part of the early and intensive motor training trial for people with SCI: a qualitative study

Jackie Chu^{1,2}, Joanne V. Glinsky^{1,2}, Hueiming Liu^{3,4}, Christine Rimmer⁵, Sharon Roberts⁵, Federica Tamburella^{6,7}, Claire Lincoln⁸, Sophia Denis⁹, Lydia W. Chen¹⁰, Donna Rainey¹¹, Vivien Jørgensen¹², Jessica van der Lede¹³, Charlotte C. M. van Laake-Geelen¹⁴, Mark McDonald¹⁵, Emilie J. Gollan¹⁶, Sue Paddison¹⁷, Chris Bell¹⁸, Kristine Oostra¹⁹, Lot Van Roey²⁰, Marsha Ben^{1,2}, Keira E. Tranter^{1,2}, Giorgio Scivoletto⁶, Annemie I. Spooren²¹, Janneke K. Stolwijk¹³ and Lisa A. Harvey^{1,2}✉

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STUDY DESIGN: A qualitative study.

OBJECTIVES: To explore participants', therapists' and stakeholders' experiences and perceptions of the trial intervention provided as part of the Early and Intensive Motor Training Trial for people with Spinal Cord Injury (SCI-MT Trial). The intervention involved 12 h per week of task specific training supplemented with strength training.

SETTINGS: Fifteen spinal injury units across Europe and Australia.

METHODS: Forty semi-structured interviews were conducted including 20 with trial participants, 16 with trial therapists and 4 with stakeholders. Interview questions were framed around the Implementation Research Logic Model and the interview guide was developed by the research team. Inductive and deductive thematic analyses were done iteratively. Trustworthiness was ensured through four criteria (credibility, transferability, dependability and confirmability).

RESULTS: Three themes were identified from these interviews, (i) the trial intervention was well received by participants and therapists, (ii) there were strengths and challenges to providing the trial intervention according to its key principles, and (iii) participants, therapists and stakeholders differed in what they felt the trial needed to demonstrate to justify the future rollout of the trial intervention.

CONCLUSIONS: There were many features of the intervention provided as part of the SCI-MT Trial that both participants and therapists valued even though the trial results indicated no therapeutic benefit. Consideration should be given to how some of these features could be better incorporated into usual care to improve patient satisfaction and engagement.

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INTRODUCTION

The Early and Intensive Motor Training Trial for people with Spinal Cord Injury (SCI) tested the effectiveness of an additional 12 h per week of task-specific training supplemented with strength training directed at and below the level of injury over a 10-week period

soon after injury [1]. The rationale for conducting the SCI-MT Trial was grounded in evidence of neuroplasticity in animal models and in the results of rehabilitation trials in other neurological conditions [2]. The SCI-MT Trial ($n = 220$) was a multi-centre, pragmatic randomised controlled trial conducted across 15 SCI

¹Kolling Institute, Faculty of Medicine and Health, The University of Sydney, Sydney, Australia. ²John Walsh Centre for Rehabilitation Research, Northern Sydney Local Health District, St Leonards, Sydney, NSW, Australia. ³The George Institute for Global Health, University of New South Wales, Sydney, Australia. ⁴Faculty of Medicine and Health, The University of Sydney, Sydney, NSW, Australia. ⁵Fiona Stanley Hospital, Murdoch, WA, Australia. ⁶I.R.C.C.S. Foundation Santa Lucia, Rome, Italy. ⁷Department of Life Sciences, Health and Health Professions, Link Campus University, Rome, Italy. ⁸Queen Elizabeth National Spinal Injuries Unit, Queen Elizabeth University Hospital, Glasgow, SCT, UK. ⁹The Prince of Wales Hospital, Randwick, NSW, Australia. ¹⁰Royal North Shore Hospital, St Leonards, NSW, Australia. ¹¹Royal Rehab, Putney, NSW, Australia. ¹²Sunnaas Rehabilitation Hospital, Nesodden, Norway. ¹³Center of Excellence for Rehabilitation Medicine, University Medical Center Utrecht Brain Center, University Medical Center Utrecht and De Hoogstraat Rehabilitation, Utrecht, the Netherlands. ¹⁴Adelante Centre of Expertise in Rehabilitation and Audiology, Hoensbroek, the Netherlands; and Department of Rehabilitation Medicine, Research School CAPHRI, Maastricht University, Maastricht, the Netherlands. ¹⁵Royal Talbot Rehabilitation Centre, Austin Health, Kew, VIC, Australia. ¹⁶The Princess Alexandra Hospital, Brisbane, QLD, Australia. ¹⁷London Spinal Cord Injury Centre, Royal National Orthopaedic Hospital Trust, Stanmore, Middlesex, UK. ¹⁸Spinal Cord Injury Rehabilitation, Repat Health Precinct, Daw Park, SA, Australia. ¹⁹Ghent University Hospital, Ghent, Belgium. ²⁰University Hospitals Leuven, Department of Physical and Rehabilitation Medicine, Leuven, Belgium. ²¹REVAL, Hasselt University, Hasselt, Belgium. ✉email: l.harvey@usyd.edu.au

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sites in Europe and Australia. The trial intervention was delivered whilst participants were receiving inpatient rehabilitation. All participants received their usual inpatient rehabilitation, while those allocated to the intervention group ($n = 109$) received an additional 12 h per week of training on top of usual inpatient rehabilitation. The task-specific training components of the additional training had to follow key principles including active voluntary muscle contractions, progression of exercises and structured weekly goal setting [3]. All therapists involved in the delivery of the additional Motor Training were trained prior to their involvement in the trial. The exercises were designed by therapists adhering to the key principles of the trial intervention. The results of the trial indicated no therapeutic benefit of the intervention on the primary outcome at 10 weeks (Total Motor Score, part of the assessment for the International Standards for Neurological Classification of Spinal Cord Injury) [4], or on any secondary outcomes at 10 weeks and 6 months. The exception was a small therapeutic effect on the psychological domain of the World Health Organisation Quality of Life – brief version (WHOQOL-BREF) at 10 weeks [2].

As part of the process evaluation conducted alongside the SCI-MT Trial [5], we conducted interviews to understand participants', therapists' and stakeholders' experiences and perceptions of the trial intervention: an additional 12 h of Motor Training per week. Gaining insight into these perspectives is important for several reasons, most notably because they may help to explain the trial's outcomes. For instance, if participants perceived the intervention as burdensome or of limited benefit, they may not have fully engaged [6]. Conversely, if therapists had difficulties delivering certain elements of the trial intervention, this could have led to poor intervention fidelity contributing to negative findings [7]. Understanding participants', therapists' and stakeholders' perceptions may also provide insights into the one positive finding: the improvement in the psychological domain of the WHOQOL-BREF at 10 weeks.

In addition to explaining the trial results, the experiences and perceptions of participants, therapists and stakeholders provide insights into how the key principles of the intervention such as goal setting and use of practice sheets were applied by therapists and experienced by participants [3]. This understanding can inform whether elements of the intervention could be incorporated into usual inpatient rehabilitation to enhance patient engagement and the overall rehabilitation processes and experiences. Moreover, the acceptability of the SCI-MT Trial intervention and how it was perceived by participants and therapists may guide future research by identifying potential challenges to implementing similar interventions.

In summary, exploring participants', therapists', and stakeholders' experiences and perceptions of the SCI-MT Trial intervention provides important context for interpreting the trial's negative findings, incorporating useful elements into current practice, and guiding future research. Therefore, this paper aims to explore and understand the experiences and perceptions of the participants, therapists, and stakeholders involved in the SCI-MT Trial.

METHODS

Data collection

A total of 40 semi-structured interviews were conducted with 20 trial participants (24 participants were approached from 11 sites), 16 trial therapists (from 10 sites) and 4 stakeholders. Stakeholders included representatives/academics from tertiary education institutes, non-hospital-based organisations and hospitals where the trial was conducted. They were not directly involved in delivering the intervention. The semi-structured interviews were based on an interview guide with questions aimed at exploring interviewees' experiences and perceptions of the trial, key principles of the trial, and probe issues that may facilitate or hinder the future roll out of the trial intervention (see Supplementary file for interview

guide) [5]. As per the United Kingdom Medical Research Council (UK MRC) guidance for process evaluation, these interviews were conducted and completed prior to knowing the trial results [8]. All interviews were conducted in English and done on a one-to-one basis from August 2023 to December 2024. Written informed consent was obtained from all interviewees. Interview duration ranged from 20–65 min. Trial therapists and stakeholders were selected by convenience sampling, with therapists approached at participating sites and stakeholders contacted through the research team's networks. Trial participants were purposively sampled by age (< 50 years of age vs ≥ 50 years of age), level of injury (tetraplegia vs paraplegia) and trial group allocation (control vs intervention) [5]. Only participants deemed to have sufficient proficiency in the use of the English language were included. Participants were interviewed a median (inter-quartile) of 26 weeks (15–45) after randomisation.

All interviewees provided consent prior to their interviews (see Tables 1 and 2 for demographic information of interviewees). All interviews were conducted by one member of the research team (JC) who was also involved as the trial coordinator. These interviews were recorded and transcribed verbatim via Microsoft Teams [9]. Another member (LAH) reviewed all transcripts after each interview and provided timely feedback and suggestions for future interviews.

Analyses

All qualitative data were managed using NVivo software [10]. Only the interviews from participants in the intervention group and all stakeholders and therapists were analysed for this paper. Both inductive and deductive thematic analyses were used, guided by the Implementation Research Logic Model to unpack the contextual determinants and mechanisms through which the intervention produced the observed outcomes (see the protocol) [5, 11, 12]. Inductive coding allowed additional codes/themes to be identified from the data including perceptions and attitudes of interviewees. Four members of the research team conducted qualitative data analysis. One member of the research team (JC) coded all 40 transcripts. Initial coding of 15 transcripts was done independently by 3 other members of the research team (LAH, JVG and HML). After initial inductive and deductive coding was completed, each member of the research team met separately with JC to discuss the 15 transcripts that were coded independently. During these meetings, codes were reviewed and re-grouped accordingly. Multiple meetings involving all 4 members were then convened to iteratively review codes, refine groupings, and identify sub-themes and themes [13]. Key themes were generated and

Table 1. Demographics of all interviewed participants and participants in the intervention group.

	Interviewed participants (n = 20)	Participants in the intervention group (n = 12)
Age (years); median (IQR)	50 (40–64)	54 (38–68)
Gender (M:F)	18:2	10:2
Age (n)		
Over 50 years old	10	6
Under 50 years old	10	6
AIS Classification (n)		
A	3	2
B	0	0
C	6	4
D	11	6
Level of Injury (n)		
Tetraplegia	10	6
Paraplegia	10	6
Group allocation (n)		
Intervention group	12	12
Control group	8	0

Table 2. Demographics of therapists and stakeholders.

	Therapists (n = 16)	Stakeholders (n = 4)
Years since qualification (years), median (IQR)	12 (7–18)	26 (20–33)
Years of experiences working in the field of SCI (years), median (IQR)	6 (3–16)	19 (14–21)
Professional background (n)		
Physiotherapists	14	3
Occupational therapists	2	-
Nurses	-	1
Professional affiliation (n)		
Tertiary education sector	-	2
Policy stakeholder	-	1
Managerial stakeholder	-	1

finalised with more discussion involving all 4 research team members. Reporting in this paper is guided by the consolidated criteria for reporting qualitative research 32 item checklist [14]. This checklist was used to guide the research team for conducting and reporting the qualitative data reported in this paper. To ensure methodological rigour and overall trustworthiness, we addressed the four established criteria of qualitative trustworthiness, namely credibility, transferability, dependability and confirmability [15]. Credibility was established through triangulation of data with four members of the team coding transcripts. The interviews were conducted by one member (JC) who also had the role of being the SCI-MT Trial coordinator. This enabled rapport building with some therapists (interviewees) involved in delivering the therapy. Dependability was established through documentation and audit trails from interview discussions and iterative discussions of codes and themes for transparency. Confirmability was established through iterative discussions between the four coders to challenge interpretations and reach consensus on themes. Transferability was established through the use of a reporting checklist which included a description of study contexts and participants.

RESULTS

The median (interquartile age) of the participants from the intervention group who were interviewed was 54 years (38–68) with a 50:50 split of tetraplegia and paraplegia (see Table 1 for details). The median (interquartile) years of experience working in SCI of the therapists and stakeholders were 6 years (3–13) and 19 years (14–21), respectively (see Table 2 for details).

The following three key themes were extracted from the qualitative data: (i) the trial intervention was well received by participants and therapists, (ii) there were strengths and challenges to providing the trial intervention according to its key principles, and (iii) participants, therapists and stakeholders differed in what they felt the trial needed to demonstrate to justify the future rollout of the trial intervention. These key themes are described in the following sections and exemplary quotes are presented in the Supplementary File.

Theme 1: high acceptability of additional motor training

Valued the protected one-to-one therapy time

Participants valued many aspects of the intervention but particularly the one-to-one attention and time they received from their therapists. They often contrasted this to the type of therapy they received as part of usual care where therapists typically manage a couple of patients at the same time in a group setting. A participant in the intervention group commented:

"I like the fact that...it was very much one-to-one...were getting a chance to really [to] talk to the person who was doing the physio and why we're doing this and what muscle groups were

working and what the advantage are of doing it. And so that was really good to be able to do that." – participant 07 (a person with paraplegia and < 50 years old).

"[In] a group setting [during usual care], so your main physio would have other patients that they were seeing...so you get set off on a task to work on...led to self-manage...but you're always sort of aware that by keeping them [the therapist] there, you're keeping them [the therapist] away from another patient...they've got other patients that they need to be dealing with." – participant 07 (a person with paraplegia and < 50 years old).

The therapists also valued the additional one-to-one time they had with the participants in the intervention group. They felt they could spend more time planning and discussing goals with participants. It also enabled them to better individualise their interventions and progress participants' exercise programs. One therapist stated:

"You can push the patients [when] you have that one-to-one protected time...you know the [patient's] ability [and can really kind of] focus in and see [this is] what we're working on." – therapist 14 (a therapist with 13 years of SCI experience).

The perceived benefits of the additional time spent with therapists were commented on in many ways. For example, participants and therapists both valued the time devoted solely to improving strength and function at and below the level of injury. In contrast to usual care, their time did not need to be shared with other aspects of rehabilitation including equipment prescription, pain management and education.

"... a lot of it [usual care] is focused on (like) doing activities... getting in and out of bed and making a transfer, brush your teeth...we have less time to really focus on the motor training, like strength training, conditioning, lots of repetitions. We cannot really offer that in our usual care." – therapist 02 (a therapist with 15 years of SCI experience).

Participants not only valued the additional one-to-one time with therapists but they also valued receiving therapy from different therapists. Different therapists were involved because the same therapists usually did not deliver usual care and the additional Motor Training. Participants appreciated the therapists' different approaches to exercise prescription and training. For example, a participant stated:

"There was one goal, my walking...getting more opinion(s) [from the different physiotherapists] is better..." – participant 09 (a person with paraplegia and > 50 years old).

Interestingly, the therapists also valued sharing the care of patients with other therapists. They talked about learning from each other. For example, one therapist stated:

"It was really nice to have lots of other therapists seeing [participants] in the evening because they would come up with different exercises. So it's like a real collaborative approach... maybe I've collected exercises from other therapists and use them with my other patients." – therapist 15 (a therapist with < 1 year of SCI experience).

Staying busy and working hard helped many participants stay motivated

Many participants enjoyed merely being kept busy by the additional Motor Training. They felt that their busy schedules

kept them motivated. They also expressed sentiments that indicated that they felt empowered by doing more for themselves and being given responsibility to work hard during the additional Motor Training sessions. Some believed that the additional Motor Training helped them to cope better with their injuries irrespective of whether it had any benefit on recovery or functional outcomes. A quote from an intervention participant illustrated this.

"...I was a lot happier in myself because I was finding that each day...as it kept going, I was just up, ready [and] eager to go every morning." – participant 18 (a person with paraplegia and > 50 years old).

But not all participants felt the same way. Some found the additional Motor Training too physically demanding and others reported problems with pain and sleep particularly during the earlier stages of their trial involvement. Nonetheless, whilst talking about some of these negative aspects of the additional Motor Training participants usually finished by talking about a sense of achievement and accomplishment that gave them satisfaction. For example, one participant said:

"...the inconvenience was a little price to pay [for] more, potentially having huge therapy gains and that chance to walk again or get stronger...It wasn't going to be easy. And I had to sacrifice some things. But the gains that I got out of it [were] outweighed any of the negatives" – participant 16 (a person with paraplegia and < 50 years old).

Participants may have tolerated the extra work associated with the additional Motor Training because generally they all held strong beliefs about the therapeutic value of the training. They reported physical and functional gains that they attributed to the additional Motor Training. For example:

"Absolutely, [that] definitely helped me...without this programme [I wouldn't] it was almost impossible...I am more independent. I can do many things myself." – participant 09 (a person with paraplegia and > 50 years old).

This was echoed by a therapist who stated:

"... overall, we see of course that more training results in better function and I can absolutely see that. And the patient says it as well." – therapist 09 (a therapist with 2 years of SCI experience).

Psychological and emotional benefits

Participants also talked about the psychological benefits of the additional Motor Training as well as its positive effects on their motivation and general mental health. For example, one participant stated:

"So those [extra] training sessions occupied most of my daily time. Makes me work on something which means I don't have time [to] be frustrated about my condition...I feel that these two months and a half, they passed so fast...It's a good point to maintain the psychological health." – participant 11 (a person with tetraplegia and < 50 years old).

Some of the therapists also pointed to a possible psychological benefit. For example:

"Psychological benefit for the patients that people know they've given 110% into their training and so they know they've potentially reached the maximum capacity that they felt really good about that." – therapist 15 (a therapist with < 1 year of SCI experience).

Overwhelmingly, participants expressed thanks and appreciation for being provided the additional Motor Training and being part of the SCI-MT Trial. Some of them described how lucky they felt being allocated into the intervention group. They felt this was a unique opportunity to do more for themselves during their rehabilitation. This was commonly perceived by participants in the intervention group despite no prior knowledge or beliefs about the possible therapeutic effect of the extra training. The quote shown here illustrates this perception.

"I was just so happy with it...it just gave me so much more confidence...at the end of the day I was feeling absolutely exhausted, but the next day I was feeling so much brighter and so much eager to keep going. I found that if I didn't have it, I think I wouldn't be as far as I am today...giving me the opportunity to do this study." – participant 18 (a person with paraplegia and > 50 years old).

Theme 2: Implementation strengths and challenges

Goal-setting as a motivating and challenging process

There were many key principles that therapists needed to adhere to when providing the additional Motor Training. For example, the training needed to be based on weekly (short-term) goals that were set by the participants with the guidance of their treating therapists during the trial period. Therapists and participants collaborated together to set goals following the SMART principles of goal setting [3]. These principles require goals to be Specific, Measurable, Attainable, Realistic and Timebound [3]. These weekly goals aimed to help participants to achieve their 10-week and 6-month (long-term) goals that were set during their initial assessments [1]. Participants often referred to this key principle and expressed varying opinions about the success of the goal-setting process. Some enjoyed setting their weekly goals because they strived to achieve them and found it motivating when they did. This is exemplified by this comment:

"...made me determined to achieve the goals...I wouldn't give up till I did achieve that goal before we moved onto another...it was great. Great motivation." – participant 14 (a person with tetraplegia and > 50 years old).

Others specifically talked about the need to have the weekly goals in addition to the long-term goals. For example, one participant said:

"Let's say I think it suits my personality...all these smaller goals, they build upon each other and at some point...you may be able to reach this far out [long-term] goal. Whereas if you immediately specify this far out [long-term] goal and then if you don't reach that goal ... you deprive yourself of all these smaller success moments and then you might be very disappointed at some point that you then don't reach that goal." – participant 06 (a person with paraplegia and < 50 years old).

The therapists also found it motivating for them to have specific goals that their participants had prioritised and were working towards. They talked about a sense of reward and satisfaction seeing participants improve and achieve their goals. Some found that this was more the case than during usual practice because they had so much one-to-one time with participants which enabled them to devote more time to the goal setting process. They felt a greater sense of continuity of care. This quote from a therapist exemplifies this sentiment:

"[The participant] wanted to play [the] piano...we set him up behind the piano with electrical stimulation and he had to hit [the] keyboard...at the end of the ten weeks, we really got [like]

his goal. And that was really fun... keep[ing] those ten-week goals at least in mind really help[ed] to breakdown what you needed for that goal and that's what we're going to focus on." – therapist 02 (a therapist with 15 years of SCI experience).

While setting goals was largely valued by participants and therapists, some therapists noticed that participants felt sad or disappointed if they did not achieve a goal. For example, a therapist stated:

"It's always good to have at least a couple [of goals] that are attainable so that they [the participants] don't get disheartened." – therapist 18 (a therapist with 2 years of SCI experience).

When asked how this was addressed, some therapists provided examples of how they modified or reviewed the weekly goals and made them less ambitious and more achievable.

"...we maybe set the bar a little lower. So she [a participant] could achieve it and keep the motivation and yeah be able to finish the 10 weeks." – therapist 09 (a therapist with 2 years of SCI experience).

Therapists also expressed difficulties setting weekly goals for participants that were very weak and unlikely to make notable improvements over the course of a week. For example, therapists stated:

"I think what the therapists had difficulties with goal setting. It was during the time when the patients if they only had very, very few muscle that were in the voluntary contraction below the level of injury." – therapist 01 (a therapist with 11 years of SCI experience).

Practice sheets as facilitators for progression and fidelity

In addition to setting goals, therapists were asked to use practice sheets in which they recorded the details of every exercise a participant performed that reflected the dosage and intensity of practice [3]. The sheets also documented weekly goals and the set-up and equipment used for each exercise, and therapists reviewed them with participants during sessions. Their primary purpose was to support therapists in setting highly specific targets for each exercise based on what the participant had done previously. Therapists commented on the usefulness of the practice sheets for this specific purpose.

"We talk[ed] about the repetitions. I go to the patient, and I say to him - today we do 20 times for four reps. I talk with the patient about the exercise, the repetition, the rests and the exercise." – therapist 05 (a therapist with 6 years of SCI experience).

In addition, they also talked about how the practice sheets enabled them to better communicate with other therapists delivering the extra training and coordinate a participant's therapy.

"We have several [therapists] across the week. Well, it's a good way to hand over to another therapist to see what, how many, what the dosage was done last time for a particular exercise." – therapist 03 (a therapist with 25 years of SCI experience).

And the therapists were clearly using the practice sheets to review participants' weekly goals, monitor participants' progress and adjust the difficulty of exercises as participants improved.

"...so that's very informative for me to see what has been working on, what has been the focus and how many repetitions

could you take there. Maybe we can do more today. We try to progress it during the week...I think they find it very motivating actually." – therapist 09 (a therapist with 2 years of SCI experience).

Therapists also liked to use the practice sheets to demonstrate progress and improvement to participants. They found that this helped maintain their own motivation as well as that of the participants. The quotes from therapists showed why they valued the use of practice sheets.

"...we actually use [practice sheets] for...a lot is taking [participants] back a few weeks and showing them what they were doing a few weeks ago in comparison to where they're at now...that's how much progress you've made and ...we might use things to then go on to set the goal." – therapist 11 (a therapist with 19 years of SCI experience).

There were many other key principles of task-specific training underpinning the additional Motor Training apart from goal setting and the use of practice sheets [3]. These included ensuring participants repeatedly practiced attempts at movements that were challenging for them, and the therapists focused on providing clear feedback, instructions and demonstration. Each exercise needed to be linked to participants' goals and targets needed to be set for each exercise each day. Adherence to some of these principles were demonstrated through statements like this:

"...maybe in the second week I can try to propose [new exercises in] because I know the [participants] and [participants'] condition better....to propose several exercises. So [yeah], there is a lot of repetition, but there is also a lot of variability." – therapist 06 (a therapist with 5 years of SCI experience).

Feasibility and suitability of additional motor training for participants

Therapists also talked about the challenges of providing enough variety in participants' exercise programs while ensuring repetitive practice. For example, they stated:

"But it's also thinking how do I achieve this in a different [way]... can I achieve the same activity but just mix it up a bit for the participants so that they don't feel like they're having to do the same exercises all the time." – therapist 14 (a therapist with 13 years of SCI experience).

Some therapists expressed frustration and/or challenges in providing 12 h of additional Motor Training for those who were very weak with limited mobility. Some even said they found treating these participants less rewarding. They spoke of primarily being able to focus on strength training rather than task-specific training because the participants were so limited in what they could do. An example from a therapist:

"...when the [participant] was getting a bit sick of the [exercises], you know potentially it's a little bit monotonous at times if you go through 4 h straight, even if you're mixing up exercises as it can get a little bit boring." – therapist 03 (a therapist with 25 years of SCI experience).

The SCI-MT Trial intervention was provided soon after participants were deemed medically stable and were able to tolerate 12 h per week of extra training for 10 weeks. Some therapists expressed a belief that this intensive training would not be suitable or tolerated by all people undergoing SCI rehabilitation. Quotes from therapists showed that they believed that the

intervention was best suited to those who were young, motivated and not in extreme psychological or emotional distress.

"...it depends a bit in the patient...the age and comorbidity and everything. I'm just thinking if some patients, maybe the older ones or the ones struggling with the fatigue and maybe a bit much to have 12 more hours in a week...those with pain and so on, but need to adjust training anyways." – therapist 10 (a therapist with 3 years of SCI experience).

This resonated with participants who also believed this extra training did not suit everyone in their SCI rehabilitation units.

"...I found that their [other patients'] attitude(s) was they just didn't want to do anything because they were perhaps [you know] slightly depressed, maybe in denial, maybe angry. And the last thing they really want to do is spend all day trying to do physical activities...whilst struggling to, you know, process, everything was going on...I don't think everyone would be able to do it just because of where they were mentally...the mental challenge is a lot for a lot of people." – participant 02 (a person with tetraplegia and < 50 years old).

However, some participants did not believe age or level of motivation would influence patients' abilities to participate in the extra training and thought everyone should be provided the option of the additional Motor Training after the completion of the trial. They felt the enjoyment they had experienced along with the therapeutic benefits were valuable and this opportunity should be provided to all.

"... you sort of have to offer it [the intervention] to everybody because it would be unfair not to." – therapist 12 (a therapist with < 1 year of SCI experience).

Theme 3: Contrasting perspectives for future rollout of the trial intervention

The participants, therapists and stakeholders/policy makers held contrasting views on the evidence needed to justify the future rollout of the trial intervention. Therapists and stakeholders/policy makers prioritised the economic case for the intervention. They felt that it was not sufficient for the trial to merely demonstrate improved quality of life or function. They felt strongly that the trial (or future work) needed to demonstrate a positive impact at the health system level such as decreased length of stay, decreased long-term care needs or increased future employment rates at the system level. The quote here illustrated this point of view.

"You need to have very clear like the study results would need to be...not just convincing, like, very convincing, like 50% of the patients who participated in the study had their care hours reduced by half or had their dependency reduced by half or their mobility improved by 50%." – stakeholder 02

Therapists' and stakeholders' were also conscious of the demands of the additional Motor Training both on the participants as well as them and the healthcare system. They inferred that the therapeutic benefits need to be evident to justify the practical challenges of changing usual care. Not surprisingly, generally the participants were less concerned about the results of the trial as justification for the trial intervention's value. Many thought everyone should be provided with the opportunity to receive the additional Motor Training. Most participants felt strongly that the extra training improved their general wellbeing and function, and had psychological benefits. They felt any gain to them justified their efforts and sacrifices in terms of loss of time spent with family and friends. To them their top priority was to gain as much improvement in their ability and function whilst

receiving their inpatient rehabilitation. They also expressed concern that the trial outcomes did not capture all the possible benefits. This intervention participant summed up his/her experiences when he/she stated:

"I think it's a good thing that [the trial] is being done. Certainly [I] hope that it results in additional time...I'm not sure that the sort of the mental health effects of being in a trial or having additional therapy and keeping people busy is factored in." – participant 13 (a person with tetraplegia and > 50 years old).

DISCUSSION

The findings presented in this paper provide insights into experiences and perceptions of participants, therapists, and stakeholders regarding the additional Motor Training delivered as part of the SCI-MT Trial. These interviews were conducted as part of the process evaluation run alongside the trial. They were conducted prior to the completion of the trial and without knowledge of the trial results. It is important to consider whether any of the identified themes provide insight as to why no treatment effect was observed for total motor score or other measures of function, mobility, and quality of life. In addition, whether the qualitative findings may offer any insights into the one positive result—the improvement observed in the psychological domain of the WHOQOL-BREF.

Despite the findings of the SCI-MT Trial, the interviews revealed valuable insights into approaches that could enhance future care. Participants clearly valued one-to-one therapy and were less enthusiastic about sharing therapists with other participants during the same session, as sometimes occurs in usual care [16, 17]. Both therapists and participants expressed a desire for dedicated time each week focused on regaining movement in muscles below the level of injury. They noted that usual care often involves managing equipment or addressing other issues, leaving limited time for this type of targeted therapy. Interestingly, both groups also identified benefits in having multiple therapists treat the same participant over the course of the trial - contrary to the common assumption that patients prefer a single consistent therapist and that therapists dislike sharing patient care [18]. The advantages and disadvantages of this approach are likely to be influenced by the personalities, skills, and attitudes of the individuals involved as well as the structure of the SCI unit. These insights suggest that inpatient SCI rehabilitation programs may benefit from restructuring usual care to provide dedicated time to focus on muscles below the level of injury and from allowing multiple therapists to treat the same patient provided clear communication systems are in place. These are some suggestions that can extend beyond the SCI-MT Trial and may inform how other SCI units and inpatient rehabilitation programs structure their usual care.

There was no indication from participants' or therapists' interviews that the intervention was perceived as burdensome, poorly tolerated or not delivered as intended: any of which could have contributed to the trial's negative results. Although some participants reported experiencing fatigue, none described missing sessions or being unable to fully engage in therapy. Therapists noted that providing 12 h of additional Motor Training was particularly challenging for participants with extensive paralysis, as these individuals were limited in what they could actively do during therapy sessions. This may have limited therapists' ability to provide 12 h per week of additional Motor Training for these participants, as specified in the trial protocol, and thereby potentially reducing the overall treatment effect. This aligns with results from our quantitative data indicating that not all participants received the full 12 h of additional Motor Training per week [2].

Several findings from the interviews may help explain the improvement observed in the psychological domain of the WHOQOL-BREF. Participants frequently described a sense of satisfaction from working hard in therapy, and expressed feeling fortunate to have access to an intervention not available to everyone [19, 20]. The increase in psychological well-being could also reflect the undivided attention participants received from dedicated therapists for 12 h each week which participants clearly valued [17, 20]. This, combined with the structure provided by clear, achievable, person-centred and individualised weekly goals, may have contributed to a sense of motivation and accomplishment [21, 22]. This reflects the importance of person-centred care with individualised goals during rehabilitation, consistent with current literature [23, 24]. Participants also suggested that being kept busy, receiving regular feedback and the intensive exercise itself could have positively influenced their mood perhaps through increased endorphin release [19]. Although these explanations are plausible, delivering additional Motor Training to all patients would be resource-intensive. Alternative strategies such as recreational therapy, music and relaxation therapy may achieve similar psychological benefits [25–27].

The interviews highlighted that participants, therapists, and stakeholders had different perspectives on what they thought the trial results needed to capture. For example, participants were equally focused on the possible physical benefits of the intervention as they were on their general feelings of wellbeing and the need to have a busy schedule and to be satisfied with the rehabilitation process. In contrast, therapists were more attuned to the practical challenges of providing such intensive training to all patients within existing healthcare systems. Stakeholders primarily focused on the possible cost–benefit of the intervention and tangible system-level benefits such as reduced hospital stays, decreased long-term care needs, or increased return to work. The stakeholders' perspectives were clearly driven by financial and resource considerations. Together, the different perspectives of the participants, therapists, and stakeholders provide insights for future trialists as to the different values that need to be captured in any trial of this kind.

This study had both strengths and weaknesses. The primary strength was its rigorous methodology; we followed a detailed protocol for the process evaluation and wrote an interview guide with clearly stated aims. Some researchers might argue that the interviews designed to inform interpretation of trial results should be conducted after the trial results are known. However, we conducted all interviews as part of the process evaluation, so it was important that they were completed before the SCI-MT Trial results were known, allowing interviewees to reflect on their recent experiences. The interviews and most of the coding were completed prior to knowledge of the trial results, reducing potential bias. We acknowledged that some participants were interviewed while still involved in the trial and some were not. This variation may have influenced participants' perceptions. However, conducting all interviews before the trial results were known ensured participants' reflections were not influenced by knowledge of the trial results. We also included a diverse range of participants, therapists, and stakeholders from multiple trial sites increasing the breadth of perspectives. Trustworthiness of these findings was enhanced through several strategies addressing credibility, dependability, confirmability and transferability [15]. A key limitation was that a single individual, who was very involved in all aspects of the trial, conducted all interviews. While her involvement provided her with extensive knowledge of trial procedures and hospital physiotherapy practices, which allowed for appropriate and insightful probing, it may also have introduced bias. As a physiotherapist, she inevitably held her own views about what does and does not work, which may have influenced both the interviews and the coding process. The other limitation was that we were unable to interview participants from

4 European sites due to language barriers. Including participants from all sites would have provided greater diversity of perspectives.

In summary, this study provides valuable insights into participants', therapists', and stakeholders' experiences of the intervention that aid interpretation of the trial results and may inform future practice. The negative findings of the SCI-MT Trial were not due to poor adherence or tolerance of the trial intervention. Both therapists and participants valued and appreciated the additional Motor Training. The findings underscore the importance of one-to-one therapy, structured goal-setting, and adequate therapy time to target movement below the level of injury, as well as the potential psychological benefits of intensive, personalised therapy. Taken together, these insights suggest that while widespread rollout of additional Motor Training may not be warranted based solely on the trial outcomes, specific elements of the intervention could be incorporated into usual care to enhance patient experience and engagement. Implementing these changes will require further work to evaluate the feasibility, benefits, and potential challenges of each element deemed valuable.

REFLEXIVITY STATEMENT

Our research team consists of academics and clinicians in the SCI field. Collectively, we bring a mix of experiences in conducting quantitative and qualitative research, as well as in the clinical management of people with SCI. The interviews were conducted as part of the process evaluation and took place over the course of the trial, prior to knowledge of the results. This timing allowed us to approach interviewees in a neutral and impartial way. To further minimise the influence of our own beliefs and assumptions, two team members reviewed the transcripts after each interview to reflect on the conduct of future interviews in an attempt to minimise the effect of our own biases. We have no conflict of interests with interviewees or with staff at the trial sites.

DATA AVAILABILITY

Data are available upon reasonable request. Deidentified participant data may be accessed by researchers who provide a methodological proposal directed to the corresponding author, LAH. Approval for data access will be granted on a case-by-case basis at the discretion of the principal investigator, LAH. 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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AUTHOR CONTRIBUTIONS

LAH, JVG, JC, MB and KET were responsible for overall trial design, day-to-day overall trial management and intervention development. JC, JVG, HML and LAH were responsible for the design of the process evaluation protocol, and the first draft of this manuscript. SR, CR, FT, CL, SD, LWC, DR, VJ, JvdL, CvL-G, MM, EJG, SP, CB, KO, LVR, GS, AIS and JMS were responsible for the sites. JVG, LAH, AIS, GS were responsible for securing funding. All authors have read and approved the final manuscript.

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COMPETING INTERESTS

The author declare no competing interests.

STATEMENT OF ETHICS

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), the Regional Committee for Medical Research Ethics South East 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). We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.

ADDITIONAL INFORMATION

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Correspondence and requests for materials should be addressed to Lisa A. Harvey.

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