Title: Efficiency of robotic gait training combined with repetitive transcranial magnetic stimulation on walking ability in patients with incomplete spinal cord injury: protocol for a feasibility study

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ABSTRACT

Introduction: Spinal cord injury (SCI) is damage to the bundles of cells and nerves that transmit incoming and outgoing information between the brain and the rest of the body. Repetitive transcranial magnetic stimulation (rTMS), combined with an exoskeleton, may restore the integrity of the corticospinal tract and promote axonal regeneration. To determine the feasibility—in terms of recruitment, intervention, and assessment—of a protocol combining repetitive transcranial magnetic stimulation with Lokomat for a randomized controlled clinical trial in patients with incomplete SCI.

Methods and analysis: This is a prospective, single-group feasibility study with pre-test and post-test design. The intervention will consist of 10 sessions over five weeks, each including 20 minutes of rTMS followed by 40 minutes of gait training. Twelve volunteers will participate. Outcomes will include recruitment rates, adherence, efficiency, acceptability, and protocol safety. The relevance of the clinical outcome measures to the study's objectives will be assessed. These measures will be collected at weeks 0, 5, and 9. Feasibility outcomes will be assessed throughout the study and reported as percentages, means, and standard deviations.

Ethics and Dissemination: Any changes to the protocol will be communicated through publication notes, written information to participants, and formal notification to the Institutional Research Ethics Committee (84401824.7.0000.5060) of the Federal University of Espírito Santo, Vitória, Brazil. The evaluator will obtain informed consent from the participant (attached file), and the participant will be free to withdraw from the study at any time. However, the data collected from this patient will be used unless requested not to be used. The results obtained from the study will be communicated to healthcare professionals and other relevant groups through publications, with dissemination of the results in a database and presentations at congresses and conferences.

STRENGTHS AND LIMITATIONS STUDY

- The study is challenging because it addresses an evolution in the parameters of the training protocol for patients after traumatic brain injury.
- It is innovative with the use of a robotic exoskeleton, Lokomat, for a population whose effects are not yet known.
- The study has specific training for patients.
- It has a small sample, which prevents extrapolation of the results.

INTRODUCTION

Spinal cord injury (SCI) is a traumatic condition affecting the spinal cord that results in the loss of motor and/or sensory function. The extent of impairment depends on the segment of the spinal cord involved and may lead to complete or partial loss of function in the upper and/or lower limbs, causing significant functional disability below the level of the lesion[1]. A lesion is considered complete when there is an absence of motor and sensory function in the sacral segments S4–S5, which are the final pairs of spinal nerves. If motor and/or sensory function is preserved post-injury, regardless of the lesion level, it is classified as incomplete[1].

Currently, the incidence of SCI is estimated at one case per 26 million inhabitants per year, with a predominance in males aged between 20 and 60 years, according to Brazil's Ministry of Health. This condition poses a substantial socioeconomic burden, with high per-patient costs[2]. Approximately 80% of SCI cases in Brazil have traumatic etiology, most commonly resulting from motor vehicle and motorcycle accidents, followed by falls[2,3]. Neuromodulation has emerged as a promising therapeutic strategy for SCI, aiming to restore corticospinal pathway integrity and promote axonal regeneration, thus reducing symptoms and/or disability[4]. Repetitive transcranial magnetic stimulation (rTMS) is a non-invasive intervention that enhances cortical activity related to motor function, supporting movement execution in individuals with central nervous system trauma[5].

rTMS has been recommended in the treatment of cognitive impairments and functional limitations in individuals with neurological and psychiatric disorders[6]. Following trauma, the nervous system undergoes dynamic plastic changes across neural networks in an attempt to adapt. Hence, an ideal therapy should consider the specific dysfunction within the nervous system, minimize or eliminate adverse effects, and be effective and cost-efficient for clinical application[6]. rTMS is particularly appealing because it is non-invasive, uses electromagnetic induction to modulate cortical activity, and is both painless and capable of deep penetration[7,8]. The most widely used modality of rTMS has demonstrated efficacy in treating conditions such as stroke, depression, Parkinson’s disease, and other central nervous system disorders[9,10,11]. Moreover, high-frequency rTMS has shown to promote axonal regeneration and extensive dendritic and axonal sprouting[12].

Treadmill training enables early gait rehabilitation by integrating weight-bearing, stepping,

and balance activities[13]. Loss of ambulation often requires caregiver support or assistive devices, as chronic gait and balance abnormalities contribute to reduced mobility, increased fall risk, and decreased quality of life[14]. Robotic gait devices such as Lokomat and GE-O were developed to address this challenge. Using Lokomat, Esquenazi et al. compared manually assisted treadmill training with robotic-assisted training and found improved gait speed and step length symmetry in the robotic group, although no significant differences were found between groups. A literature search was conducted using PubMed, Cochrane, and PEDro databases. While some studies have evaluated rTMS or robotic gait training individually in post-SCI populations, none have explored the combined approach proposed in this study. Thus, this protocol aims to assess the feasibility of combining rTMS with Lokomat-assisted gait training in individuals with SCI. The outcomes of this feasibility study will inform the design of a definitive trial evaluating improvements in gait speed and social participation related to quality of life.

This is a protocol study. The objective of the feasibility trial is to evaluate the feasibility of combining rTMS with Lokomat-assisted gait training to improve ambulation in individuals with incomplete SCI. The findings will support the design of a subsequent trial exploring the full therapeutic potential of this combined approach, aiming to improve gait speed and associated social participation and quality of life. The specific research questions are: What are the recruitment rate, attendance, adherence, efficiency, safety, and acceptability of the proposed protocol? Is there any benefit in quality of life and gait as measured by the Walking Index for Spinal Cord Injury II (WISCI II) and Spinal Cord Independence Measure (SCIM III) scales?

METHODS AND ANALYSIS

Trial design

The protocol for this feasibility study will be a single-group study. The study received ethical approval from the Institutional Research Ethics Committee ((84401824.7.0000.5060) of the Federal University of Espírito Santo, Vitória, Brazil.

Study setting

The study will be carried out at the Interprofessional Health School Clinic of the Universidade Federal do Espírito Santo, located in Vitória, Espírito Santo, Brazil.

Participants and therapists—inclusion and exclusion criteria

To be included in the study, participants must have sustained an incomplete spinal cord injury and meet the following eligibility criteria: be between 16 and 60 years of age; of either sex; classified as level B, C, or D according to the ASIA Impairment Scale.

Patient and Public Involvement

Patients with incomplete spinal cord injury and their families are not involved in defining the research question or outcome measures, but they are involved in improving the intervention protocol and its acceptability in terms of the number of sessions, fatigue, and interest and satisfaction. Patients and their families may also contribute to disseminating information about the implementation of the protocol to the target community and enhancing the recruitment of new patients.

Intervention

The group will carry out the intervention twice a week, and the study will take place over five weeks, totaling ten sessions. Each session will consist of 30 minutes of TMS stimulation prior to gait training on the Lokomat, which will last 40 minutes.

Before the intervention begins, participants will undergo an assessment aimed at preparing the equipment. For rTMS, markings will be made on the cap based on the participant's skull. Additionally, information such as weight, height, femur length, age, and leg length will be used to determine the appropriate equipment size for the Lokomat intervention.

The purpose of rTMS is to stimulate the brain to facilitate gait training by enhancing the neuronal response to exercise. An excitatory protocol of 10 hertz, 50 pulses, 30 trains, and 20 seconds will be applied over the motor area M1 (motor cortex) at a 45° angle[15]. The stimulation will be performed with the patient seated, using an individual white cap marked according to the 10–20 system (Figure 1). After the stimulation, the patient will undergo 30 minutes of gait training, which is commonly reported in the literature as the minimum time

required for training, although there is no defined optimal duration for Lokomat use to achieve results[16].

An additional 30 minutes will be allocated for donning and doffing the equipment during the first session; from the second session onward, this time will be reduced to 15 minutes. During the first session, participants will be introduced to the equipment and receive a brief and simple explanation of its function and the training process.

On the first day of training with the Lokomat Nanos (Hocoma, Switzerland), femur and leg lengths will be measured. These parameters will then be entered into the equipment, and a file will be created for each patient including name, age, height, weight, diagnosis (spinal cord injury), identification number, and the parameters mentioned above. The brace sizes for thigh, calf, and ankle will be individually adjusted. Due to the detailed fitting process, as previously mentioned, 30 minutes will be allocated to properly fit the patient into the device before starting the training.

The first week of training will be used to adapt the patient to the device, ensure proper fitting of the orthosis, and allow the patient to understand the gait process. The goal is to complete the full 30-minute training sessions using the initial speed measured by the 10-Meter Walk Test, with 50% body weight support and 100% guidance force from the device. No parameters will be modified during the first week to allow for adaptation.

From the second week onward, parameters will be adjusted. Body weight support will start at 50% and will be reduced by 5 kg each week. If the therapist determines the participant can reduce support earlier, this will be done, potentially reaching 0% support. Impedance (i.e., how much the patient is free to move) will start at 100% device control in the first week and be reduced by 10% per week based on the patient's performance, potentially down to 0%. Speed will begin at the rate determined by the 10-Meter Walk Test and will increase according to the therapist's evaluation, aiming to reach the patient's maximum capacity. Since the 10-Meter Walk Test measures speed in m/s and Lokomat uses km/h, conversions will be applied, but results will be reported in m/s.

Throughout training, physical therapists will provide predefined positive verbal cues such as

“You’re doing great,” or “Keep it up, this is excellent.” If the patient reports fatigue, new encouragement will be given, like “Let’s go, just a little more,” or “We’re almost there.” After two such prompts, if fatigue is still reported, the exercise will be paused, but the patient will remain standing in the device. If possible, the training will resume and continue for the remaining session time.

It is important to note that the patient may pause the session only twice. If a third pause is needed, the session will be terminated and considered complete. All pauses will be recorded and documented. Furthermore, any adverse events such as nausea, dizziness, extreme fatigue, fainting, injury from the harness, muscle or joint pain, tendon inflammation, excessive strain on the musculoskeletal system, or other unforeseen effects will be documented for later analysis.

Outcomes

Primary Outcomes

Primary outcomes of interest will be: recruitment, attendance, adherence, efficiency, acceptability, and safety.

Recruitment will be determined by the proportion of participants contacted, through lists of previous or running projects and advertisements, and by evaluating the rates of refusals to participate in training or further ineligibility commonly reported. The interpretation of these data is to understand if inclusion and/or exclusion criteria or recruitment sources are sufficient to include more participants in a future project. Efficient recruitment sources will be used for future recruitment.

Attendance will be determined by the proportion of participants that attended evaluations and walking training sessions. Participants are supposed to attend 10 planned sessions. Participants who attended less than 50% of training sessions were classified as “poor attenders”[17].

Adherence will be determined by the proportion of participants that completed the training. The number of sessions where the participant completed the full 30 minutes of walking training and the reasons for not completing the 30 minutes, will be noted. This information will be used to determine: i) the number of sessions where the participant completed the full

training; and ii) the reasons for not completing the full training protocol.

Efficiency will be determined by comparing training parameters such as walking speed, orientation force and weight support offered at the end of the training protocol, thus obtaining an average of how much these parameters are increased or reduced for the last two respectively.

Acceptability will be assessed through the questions answered within a questionnaire presented in Table 3, and then the proportion of these responses will be evaluated. If at least 50% of the responses are affirmative, then it will be considered a positive response regarding the acceptability of the training.

Safety will be defined through the number of adverse events that occurred during training or shortly after, within the total number of sessions to be carried out.

Data instruments

The data instruments will be: gait speed, step length, mobility, independence in daily activities and mobility, changes in cortical excitability, quality of life, and social participation. The assessments will be conducted at baseline, after five weeks (end of the intervention), and one month after the end of treatment (follow-up).

Gait speed will be measured using the 10-Meter Walk Test. Gait speed will be calculated by dividing the distance covered, i.e., 10 meters, by the time taken to cover the distance, and will be reported in meters per second (m/s). Step length will be calculated by dividing the distance covered, i.e., 10 meters, by the number of steps taken to cover the distance, and will be reported in meters. Gait cadence will be calculated by dividing the number of steps by the time taken to cover the distance, i.e., 10 meters, and will be reported in steps per minute. The 10-Meter Walk Test will be performed in a 14-meter corridor, with 2 meters for acceleration and 2 meters for deceleration[18]. After one practice trial, the value obtained during a single test will be used for analysis[19].

The Walking Index for Spinal Cord Injury II (WISCI II) assesses the amount of physical assistance and devices needed to walk after paralysis resulting from spinal cord injury (SCI). They are designed to be a more accurate measure of improvement in specific walking ability. Consider the amount of assistance: two people, defined as moderate to maximum assistance; 1

person, defined as minimal assistance; no assistance; assistive devices such as parallel bars, walker, crutches (axillary or forearm), canes. Also consider orthodontic appliances: 1 or 2; short or long. It is important to note that the original WISCI scale consists of items 1 to 20; the scale was revised for WISCI II to include items 0 to 20.[20]

To assess independence in daily activities and mobility in individuals with spinal cord injury, the Spinal Cord Independence Measure (SCIM III) will be used. The SCIM III evaluates levels of independence in performing activities of daily living and mobility for individuals with spinal cord injury. It is divided into three supplementary subscales: "self-care," which assesses six tasks and is scored from 0 to 20; "respiration and sphincter management," scored from 0 to 40 across four tasks; and "mobility," scored from 0 to 40 across nine tasks. The total score ranges from 0 (most dependent) to 100 (most independent). The SCIM III should be administered by a professional familiar with the instrument and with spinal cord injury rehabilitation, although no prior training is required. Responses may be obtained through interviews or direct observation of the individual while performing the listed tasks. The health professional administering the test should seek the most accurate information regarding the person's actual level of independence in daily life. It has become standard practice that, when individuals demonstrate two different levels of independence for a given task depending on the time of day or other contextual factors, the lower level is used to determine the final score.[21]

Data Management

The evaluated physiotherapists will be trained by therapists with at least three years of experience and the professionals responsible for walking training on the equipment will be carried out by physiotherapists who have undergone training provided by the company or who have received training from physiotherapists already trained by the company. In this way, the data will be collected and stored in tables that will receive information and conferences from at least two physiotherapists every month, to carry out an audit on the results of recruitment, evaluations and the implementation of interventions with patients. Further details will be provided upon request to the study authors. A committee for data monitoring is not necessary due to the nature of the feasibility study and its way of collecting and analyzing statistical data. If it is necessary to interrupt the research, the authors will be responsible for making the decision on what will be done with the provisional data and on the completion of the project.

Allocation and Randomization

Participants will be allocated to a single group, no type of randomization will be performed. Furthermore, there is no blinding of any of the parties involved, either the recruiters and physiotherapists responsible for assessment and training, or the patients themselves. Figure 1 presents the study flowchart, detailing the recruitment steps, participant allocation, interventions applied and data analysis.

Sample Size

Due to the nature of the feasibility study, it may not be possible to calculate the sample size[22].Therefore, based on the recommendations for pilot studies where it is not possible to calculate the sample size, a flat rule of thumb can be used according to Kunselman (2024), approximately 12 participants can be used in each group[22,24]. The objective is to be able to find the results that are desired to obtain with the feasibility of this study[23].

Data Analysis

Due to the nature of a feasibility study, no formal sample size calculation was performed. Our goal was to include 20% of the total number of recruited individuals and sessions initially planned. Due to the nature of the study, it will not have statistical power to detect clinically significant differences between groups in the outcomes assessed[24,25]. For participant characteristics and feasibility results, descriptive statistics are presented as mean (SD) or percentage (%), as well as the number of representations[24,25]. Thus, the recruitment rate will be positive if at least 20% of the sample is eligible for the study and is willing to participate. Adherence will be positive if at least 50% of the sessions are completed by the end of the protocol, while efficiency will be determined by determining the mean values of increase in speed and reduction in driving force and weight support, with an ideal improvement greater than or equal to 20%. Regarding acceptability, it will be good if at least 50% of the questionnaire responses are positive. Safety will be defined by the number of adverse events occurring during all training sessions, being expected to be less than or equal to 5%. Regarding the data instruments, the results will be demonstrated by mean and standard deviation for pre- and post-test and follow-up differences, for gait speed, mobility and scores in the domains of the spinal cord independence measure.

ETHICS AND DISSEMINATION

Possible modifications to the protocol, such as changes to eligibility criteria, results and analyses, will be communicated through a note in the publication, written information to

participants and regulations to the ethics board. The evaluator will obtain informed consent from the participant (attached file) and the participant will be free to withdraw from the study at any time, but data collected from this patient will be used unless there is a request that it not be used.

The reliability of the data is that only researchers have full access to the study data, which is kept in a secure location. Data will be available to authors upon reasonable request, but any information related to participant identification will be withheld. The results obtained through the study will be communicated to healthcare professionals and other relevant groups through publications, reporting the results in a database and presenting them at congresses and conferences.

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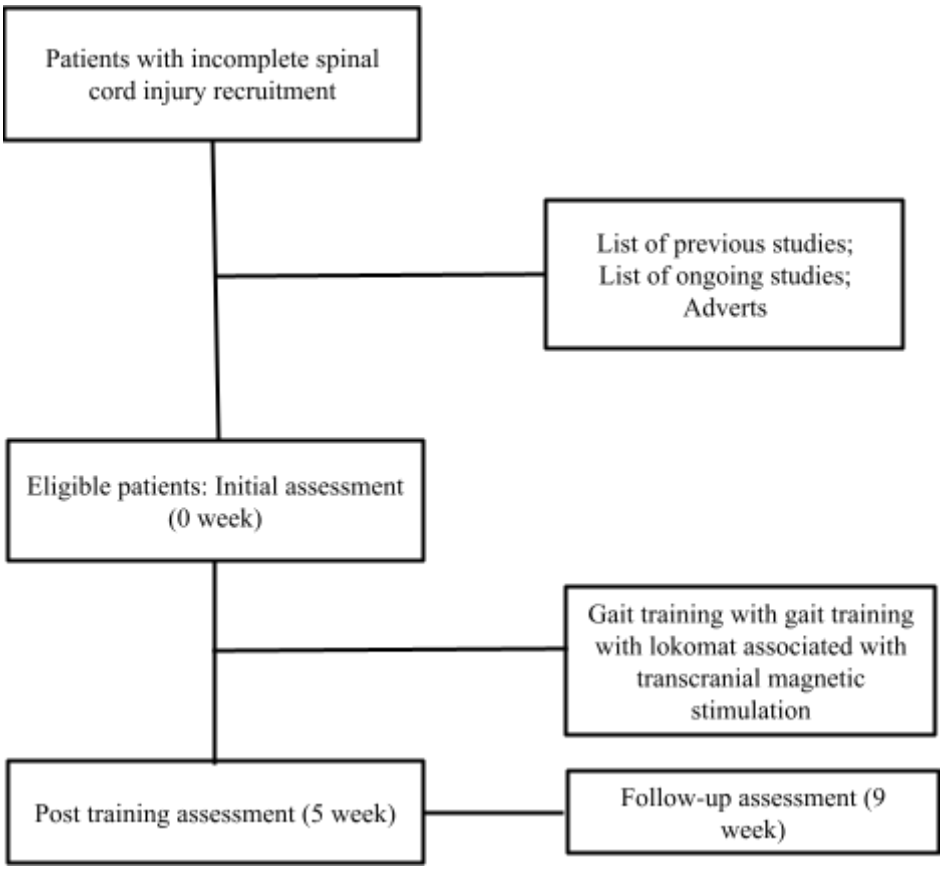
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Figure

Figure 1: Fluxograma



Tables

Table 1. Exclusion criteria

Exclusion criteria	
Weight	>135 Kg
Height	>1.90m
Femur length	<35 cm or >47cm
Suffer from unstable cardiovascular disease	Arterial hypertension, acute myocardial infarction, acute thromboembolic disease, among other factors.
Musculoskeletal system	Patients who have severe contractures in the lower extremities; bone instability; non-union fractures; osteoporosis; severe discrepancy in the length of the lower limbs;osteomyelitis.
Skin conditions that prevent the placement of armor	unhealed skin lesions; colostomy bags, urinary tract catheters.
Respiratory system	mechanical ventilation
Conditions that preclude active rehabilitation	Pregnancy, infections, inflammatory disorders, uncontrolled chronic conditions.
kidney disease	patient undergoing hemodialysis
Training on lokomat	patients who have already undergone training on Lokomat.

Table 2. Google-forms evolution diary.

Evolution diary

Patient:

Identification No.:

	Day:	Time:
New Week:	Yes ( )	No ( )
Weight support: Walking speed: Guidance Force: Placing time on the device:	Intial:	End:
Training time:	Total time	Stop time
Adverse event?	yes/ no	What/Wich?

Table 3. Acceptability of walking training on the Lokomat for patients.

Acceptability	**yes**	**No**

Would you recommend this training to a friend who has suffered a TBI?	( )	( )
Did you feel tired from training?	( )	( )
Are you satisfied with the training you received?	( )	( )
Would you carry out training with a greater number of sessions?	( )	( )
Is this training interesting for you?	( )	( )

Walking Index for Spinal Cord Injury I

Physical limitation for walking secondary to impairment is defined at the person level and indicates the ability of a person to walk after spinal cord injury. The development of this assessment index required a rank ordering along a dimension of impairment, from the level of most severe impairment to least severe impairment based on the use of devices, braces and physical assistance of one or more persons. The order of the levels suggests each successive level is a less impaired level than the former. The ranking of severity is based on the severity of the impairment and not on functional independence in the environment. The following definitions standardize the terms used in each item:

Physical assistance:

'Physical assistance of two persons' is moderate to maximum assistance
'Physical assistance of one person' is minimal assistance.

Braces:

'Braces' means one or two braces, either short or long leg.

'No braces' means no braces on either leg.

Walker:

'Walker' is a conventional rigid walker without wheels.

Crutches:

'Crutches' can be Lofstrand (canadian) or axillary

Cane:

‘Cane’ is a conventional straight cane.

Level Description

1 = Ambulates in parallel bars, with braces and physical assistance of two persons, less

than 10 meters.

2 = Ambulates in parallel bars, with braces and physical assistance of two persons, 10 meters.

3 = Ambulates in parallel bars, with braces and physical assistance of one person, 10 meters.

4 = Ambulates in parallel bars, no braces and physical assistance of one person, 10 meters.

5 = Ambulates in parallel bars, with braces and no physical assistance, 10 meters. 6 = Ambulates with walker, with braces and physical assistance of one person, 10 meters.

7 = Ambulates with two crutches, with braces and physical assistance of one person, 10 meters.

8 = Ambulates with walker, no braces and physical assistance of one person, 10

meters.

9 = Ambulates with walker, with braces and no physical assistance, 10 meters. 10 = Ambulates with one cane/crutch, with braces and physical assistance of one person, 10 meters.

11 = Ambulates with two crutches, no braces and physical assistance of one person, 10 meters.

12 = Ambulates with two crutches, with braces and no physical assistance, 10 meters.

13 = Ambulates with walker, no braces and no physical assistance, 10 meters. 14 = Ambulates with one cane/crutch, no braces and physical assistance of one person, 10 meters.

15 = Ambulates with one cane/crutch, with braces and no physical assistance, 10 meters.

16 = Ambulates with two crutches, no braces and no physical assistance, 10 meters. 17 = Ambulates with no devices, no braces and physical assistance of one person, 10 meters.

18 = Ambulates with one cane/crutch, no braces and no physical assistance, 10 meters.

19 = Ambulates with no devices, no braces and no physical assistance, 10 meters

Levels:

Level	Devices	Braces	Assistance	Distance
1	Parallel bars	Braces	2 persons	Less than 10 meters
2	Parallel bars	Braces	2 persons	10 meters
3	Parallel bars	Braces	1 person	10 meters

4	Parallel bars	No braces	1 person	10 meters
5	Parallel bars	Braces	No assistance	10 meters
6	Walker	Braces	1 person	10 meters
7	Two crutches	Braces	1 person	10 meters
8	Walker	No braces	1 person	10 meters
9	Walker	Braces	No assistance	10 meters
10	One cane/ crutch	Braces	1 person	10 meters
11	Two crutches	No braces	1 person	10 meters
12	Two crutches	Braces	No assistance	10 meters
13	Walker	No braces	No assistance	10 meters
14	One cane/ crutch	No braces	1 person	10 meters
15	One cane/ crutch	Braces	No assistance	10 meters
16	Two crutches	No braces	No assistance	10 meters
17	No devices	No braces	1 person	10 meters
18	One cane/	No braces	No assistance	10 meters

	crutch			
19	No devices	No braces	No assistance	10 meters

Walking Index for Spinal Cord Injury:

Check descriptors which apply to current walking performance, then assign the highest level of walking performance.

In scoring a level, one should choose the level at which the patient is safe as judged by the therapist, with patient's comfort level described. If devices other than stated in the standard

definitions are used, they should be documented as descriptors. If there is a discrepancy between two observers, the higher level should be chosen.

Descriptors

Devices	Braces	Assistance	Patient reported comfort level
Parallel bars < 10 ft	Long Leg Braces Uses 2 Uses 1	Max assistance x 2 people	Very comfortable
Parallel bars 10 ft	Short Leg Braces Uses 2 Uses 1	Min/mod assistance x 2 people	Slightly comfortable
Walker – Standard rolling platform		Min/mod assistance x 1 person	Neither comfortable or uncomfortable
Crutches – Uses 2 Uses 1			Slightly uncomfortable
Canes – Quad Uses 2 Uses 1			Very uncomfortable
No devices	No braces	No assistance	

WISCI Levels:

Level	Devices	Braces	Assistance	Distance
1	Parallel bars	Braces	2 persons	Less than 10 meters
2	Parallel bars	Braces	2 persons	10 meters
3	Parallel bars	Braces	1 person	10 meters
4	Parallel bars	No braces	1 person	10 meters
5	Parallel bars	Braces	No assistance	10 meters
6	Walker	Braces	1 person	10 meters
7	Two crutches	Braces	1 person	10 meters
8	Walker	No braces	1 person	10 meters
9	Walker	Braces	No assistance	10 meters
10	One cane/	Braces	1 person	10 meters

	crutch			
11	Two crutches	No braces	1 person	10 meters

12	Two crutches	Braces	No assistance	10 meters
13	Walker	No braces	No assistance	10 meters
14	One cane/ crutch	No braces	1 person	10 meters
15	One cane/ crutch	Braces	No assistance	10 meters
16	Two crutches	No braces	No assistance	10 meters
17	No devices	No braces	1 person	10 meters
18	One cane/ crutch	No braces	No assistance	10 meters
19	No devices	No braces	No assistance	10 meters

WISCI Level assigned: _____

Spinal Cord Independence Measure

For each item, mark the option next to the statement that best expresses your current situation. Your responses should mention your situation, as well as whether you currently face health problems that limit your current independence.

Please read the text carefully and mark only one option in each section.

1. Eating and drinking

[0] [ ] I require artificial feeding or use a gastric tube for feeding.

[0] [ ] I require total assistance when eating/drinking.

[1] [ ] I require some assistance when eating/drinking or when putting on/taking off adaptive devices.

[2] [ ] I eat/drink independently, but I require adaptive devices or help when cutting food, pouring drinks, or opening containers.

[3] [ ] I eat/drink independently without assistance or adaptive devices.

2A. Washing your upper body and head

Washing your upper body and head includes soaping yourself, drying yourself, and turning the tap/water valve on/off.

[0] [ ] I need full assistance.

[1] [ ] I need some assistance.

[2] [ ] I am independent, but require adaptive devices or specific equipment (e.g., grab bars, chair).

[3] [ ] I am independent and do not require adaptive devices or specific equipment.

2B. Washing your lower body

Washing your lower body includes soaping yourself, drying yourself, and turning the tap/water valve on/off.

[0] [ ] I need full assistance.

[1] [ ] I need some assistance. [2] [ ] I am independent, but I need adaptive devices or specific equipment (e.g., bars, chair).

[3] [ ] I am independent and do not need adaptive devices or specific equipment.

3A. Dressing your upper body

Dressing your upper body includes putting on and taking off clothing such as shirts, blouses, shirts, bras, shawls, or orthotics (e.g., arm splint, neck brace, abdominal brace).

- Easy-to-put-on clothing is clothing without buttons, zippers, or ties.

- Difficult-to-put-on clothing is clothing with buttons, zippers, or ties.

[0] [ ] I need some help.

[1] [ ] I need some help, even with easy-to-put-on clothing.

[2] [ ] I do not need help with easy-to-put-on clothing, but I do need adaptive devices or specific equipment. [3] [ ] I am independent with easy-to-put-on clothes and only require help or adaptive devices or a specific adjustment with difficult-to-put-on clothes.

[4] [ ] I am completely independent.

3B. Dressing your lower body

Dressing your lower body includes putting on and taking off clothes such as shorts, pants, shoes, socks, belts or orthoses (e.g. knee/ankle braces).

- Easy-to-put-on clothes are those without buttons, zippers or ties.

- Difficult-to-put-on clothes are those with buttons, zippers or ties.

[0] [ ] I require complete help.

[1] [ ] I require some help, even with easy-to-put-on clothes.

[2] [ ] I do not need help with easy-to-put-on clothes, but I do need adaptive devices or specific equipment.

[3] [ ] I am independent with easy-to-put-on clothes and only need help or adaptive devices or specific adjustment with difficult-to-put-on clothes.

[4] [ ] I am completely independent.

4. Personal hygiene

Please think about activities such as washing your hands and face, brushing your teeth, combing your hair, shaving or putting on make-up.

[0] [ ] I need full help.

[1] [ ] I need a little help.

[2] [ ] I am independent using adaptive devices.

[3] [ ] I am independent without adaptive devices.

5. Breathing

I need a breathing tube (tracheal)...

[0] [ ] and assisted ventilation either permanently or occasionally.

[2] [ ] and supplemental oxygen as well as a lot of help with coughing or handling the breathing tube.

[4] [ ] and little help with coughing or handling the breathing tube.

I do not require a breathing tube (tracheal)...

[6] [ ] but I require supplemental oxygen or a lot of help with coughing or a ventilation mask (e.g., PEEP) or assisted ventilation from time to time (e.g.,

BIPAP).

[8] [ ] and only a little help or stimulation with coughing.

[10] [ ] and I can breathe and cough independently without any help or adaptation device.

6. Bladder control

Please think about the way you empty your bladder. [Scoring for item 6: see Appendix B].

6A. Use of a urinary catheter

[0] [ ] Yes – Please go to question 7A. [1] [ ] No – Please also answer questions 6B and 6C.

6B. Intermittent catheterization

[0] [ ] I need full assistance.

[1] [ ] I do it myself with assistance (self-catheterization).

[2] [ ] I do it myself without help (self-catheterization).

[3] [ ] I do not use it.

6C. Use of external drainage devices (e.g., urine collectors, diapers, sanitary napkins, etc.)

[0] [ ] I need full help to insert them.

[1] [ ] I need some help to insert them.

[2] [ ] I insert them without help.

[3] [ ] I have urinary control and do not use external drainage devices.

7. Bowel control [Score for item 7: see Appendix C].

7A. Do you require help with bowel control (e.g., with suppository insertion)?

[0] [ ] Yes

[1] [ ] No

7B. My bowel movements are...

[0] [ ] irregular or infrequent (less than once in 3 days).

[1] [ ] regular (once every 3 days or more).

7C. Leakage of stool ("accidents") happens...

[0] [ ] twice a month or more.

[1] [ ] once a month.

[2] [ ] never happens.

8. Toilet use

Please think about using the toilet, cleaning your genital area and hands, putting on and taking off clothes, and using pads or diapers.

[0] [ ] I need full help.

[1] [ ] I need a little help and I can’t clean myself.

[2] [ ] I need some help and can clean myself.

[4] [ ] I do not need help, but I do need assistive devices (e.g., grab bars) or a specially adjusted location (e.g., wheelchair-accessible bathroom).

[5] [ ] I do not need any help, assistive devices, or a specially adjusted location.

9. How many of the following four activities can you do without help or electrical devices?

- Roll your upper body in bed.

- Roll your lower body in bed.

- Sit up in bed.

- While sitting in a wheelchair, lift your upper body up using your arms (with or without assistive devices).

[0] [ ] None, I need help with all of these activities.

[2] [ ] One.

[4] [ ] Two or three.

[6] [ ] All activities.

10. Transferring from bed to wheelchair

[0] [ ] I require full assistance.

[1] [ ] I require some assistance, supervision or adaptive devices (e.g. transfer board).

[2] [ ] I do not require any assistance or adaptive devices.

[2] [ ] I do not use a wheelchair.

11. Transferring from wheelchair to toilet/bath

Transferring also includes transferring from wheelchair or bed to shower chair.

[0] [ ] I require full assistance.

[1] [ ] I require some assistance, supervision or adaptive devices (e.g. grab bars).

[2] [ ] I do not require any assistance or adaptive devices.

[2] [ ] I do not use a wheelchair.

12. Moving around indoors

I use a wheelchair. And to move around...

[0] [ ] I require full assistance.

[1] [ ] I need a power wheelchair or some assistance in operating a manual wheelchair.

[2] [ ] I am independent in a manual wheelchair.

I walk indoors and I...

[3] [ ] I need supervision while walking (with or without the aid of a walker).

[4] [ ] I walk with a walker or crutches, rocking forward with both feet at the same time.

[5] [ ] I walk with crutches or two canes, placing one foot in front of the other.

[6] [ ] I walk with a cane.

[7] [ ] I walk with a leg brace only (e.g. a knee or ankle brace).

[8] [ ] I walk without the aid of a walker.

13. Moving moderate distances (10 to 100 meters)

I use a wheelchair. And to move...

[0] [ ] I need full assistance.

[1] [ ] I need a motorized wheelchair or some assistance to operate a manual wheelchair.

[2] [ ] I am independent with a manual

wheelchair. I walk moderate distances and I...

[3] [ ] I need supervision while walking (with or without the assistance of walkers).

[4] [ ] I walk with a walker or crutches, rocking forward with both feet at the same time.

[5] [ ] I walk with crutches or two canes, placing one foot in front of the other.

[6] [ ] I walk with a cane.

[7] [ ] I walk with a leg brace only (e.g., a knee or ankle brace).

[8] [ ] I walk without the aid of a walker.

14. Moving outdoors for more than 100 meters

I use a wheelchair. And to move...

[0] [ ] I need full assistance.

[1] [ ] I need an electric wheelchair or some assistance to move a manual wheelchair.

[2] [ ] I am independent with a manual wheelchair.

I walk for more than 100 meters and I...

[3] [ ] I need supervision while walking (with or without the aid of a walker).

[4] [ ] I walk with a walker or crutches, rocking forward with both feet at the same time.

[5] [ ] I walk with crutches or two canes, placing one foot in front of the other.

[6] [ ] I walk with one cane.

[7] [ ] I walk with a leg brace only (e.g., a knee or ankle splint).

[8] [ ] I walk without the aid of a walker.

15. Going up or down stairs

[0] [ ] I am unable to go up and down

stairs. I can go up and down at least 3

steps...

[1] [ ] but only with help or supervision.

[2] [ ] but only with assistive devices (e.g., handrail, crutches, or cane).

[3] [ ] without any help, supervision, or device.

16. Transferring from wheelchair to car

Transferring also includes getting the wheelchair in and out of the car.

[0] [ ] I require full assistance.

[1] [ ] I require some assistance, supervision, or adaptive devices.

[2] [ ] I do not require any assistance or adaptive device.

[3] [ ] I do not use a wheelchair.

17. Transfer from floor to wheelchair

[0] [ ] I require assistance.

[1] [ ] I do not require any assistance.

[1] [ ] I do not use a wheelchair.

study schedule

Start date	End date	Action
March/2024	March/2025	Literature Review.
March/2024	October/2024	Project Development and Submission to the Research Ethics Committee.
December/2024	November/2025	Participant Recruitment and Selection Based on Inclusion and Exclusion Criteria.
August/2025	December/2026	Training and Data Collection.
February/2025	February/2026	Data Analysis and Results Preparation.
December/2025	March/2026	Project completion.
March/2026	March/2026	Final Report Preparation and Article Submission for Publication.