


# Evaluation of the feasibility and acceptability of a home-based supervised exercise programme in individuals with spinal cord injuries: SCI-HOME-ACTIVE study protocol

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## ABSTRACT

Physical activity is essential to a healthy lifestyle for adults with spinal cord injuries (SCI). Although exercise is recognised as an important tool for improving the well-being and independence of people with SCI, most individuals do not engage in physical exercise. Traditional exercise programmes often require participation in rehabilitation centres or specialised facilities, making them less accessible for individuals with chronic SCI. Many people with SCI live in rural communities and other geographically isolated areas where access to fitness facilities and outdoor recreational areas involves long commutes or expensive transportation, which is one of the most common barriers to exercise reported by people with physical disabilities. Consequently, exercise remains an underused intervention for improving health and function in people with SCI despite its proven effects in reducing pain, fatigue, fall risk and other secondary health conditions. This pilot study evaluates the feasibility and acceptability of a home-based supervised exercise programme for individuals with chronic SCI. The study will be an interventional and prospective pilot study. People with SCI will participate in a 3-month home-based exercise programme. Primary outcomes will include adherence to the exercise programme, while secondary outcomes will encompass quality of life, functional capacity, musculoskeletal health and clinical parameters. The programme will be structured into 1-hour sessions, held twice weekly for 3 months, conducted online and in small groups. The results of this study could be relevant for future indications of the best setting and strategy to ensure adherence to physical activity.

## INTRODUCTION

Spinal cord injury (SCI) is a dramatic condition that can lead to death or severe and permanent disability for affected individuals, resulting not only in physical damage but also in serious psychological, quality of life and financial burdens for the individual and their family. Injuries can be traumatic or non-traumatic in origin. Traumatic causes

## WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Physical activity (PA) is crucial for improving well-being and independence in individuals with spinal cord injuries (SCI). However, traditional exercise programmes often require participation in specialised facilities, making them less accessible, particularly for those in rural or geographically isolated areas.

## WHAT THIS STUDY ADDS

⇒ This study will evaluate the feasibility and acceptability of a home-based supervised exercise programme for individuals with chronic SCI, providing an alternative to traditional facility-based programmes. By integrating specialised personnel to supervise exercise sessions online, the study aims to increase the accessibility and adherence to PA among this population.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The findings from this study will contribute to the evidence base for home-based exercise interventions, potentially influencing future guidelines and policies for PA promotion in individuals with SCI. This could support the development of more accessible and effective exercise programmes, especially for those living in rural and isolated areas.

include motor vehicle accidents, workplace falls, acts of violence and sports/recreational activities. In contrast, non-traumatic causes can be vascular, infectious, neoplastic, degenerative, etc.<sup>1</sup> SCIs bring about disability and severe consequences, causing diminished or complete loss of movement, feeling, and involuntary functions below the site of the injury.

Furthermore, those enduring long-term SCIs frequently encounter decreased mobility and physical capacity, greatly affecting their overall well-being. Additionally, sedentary habits resulting from these injuries affect



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individuals' fitness and quality of life.<sup>2,3</sup> Consequently, they face heightened risks of developing type 2 diabetes,<sup>4</sup> cardiovascular disease<sup>5,6</sup> and metabolic syndrome.<sup>7</sup> Therefore, promoting an active lifestyle for individuals with SCI is important for preventing secondary consequences of SCI. In recent years, the use of physical exercise as a key component in the rehabilitation of people with SCI has gained increasing attention. Indeed, physical exercise is the only known intervention that can have lasting effects on function after SCI, promoting neural recovery and reducing secondary complications. Physical activity is an essential part of a healthy lifestyle for adults with SCIs. Guidelines on physical activity and sedentary behaviour published by WHO highlight that people living with SCI should do at least 150–300 min of moderate-intensity aerobic physical activity or at least 75–150 min of vigorous-intensity aerobic physical activity or an equivalent combination of moderate-intensity and vigorous-intensity activity throughout the week for substantial health benefits.<sup>8</sup> Although it is recognised that an exercise is an important tool for improving the well-being and independence of people with SCIs, most individuals with SCIs do not engage in any physical exercise.

However, traditional exercise programmes often require participation in rehabilitation centres or specialised facilities, making them less accessible for individuals with chronic SCI. Many people with SCI live in rural communities and other geographically isolated areas where access to fitness facilities and outdoor recreational areas involves long commutes or expensive transportation, which is one of the most common barriers to exercise reported by people with physical disabilities.<sup>9</sup> Consequently, exercise remains an underused intervention for improving health and function in people with SCI despite its proven effects in reducing pain, fatigue, fall risk and other secondary health conditions.<sup>10–12</sup> Latimer *et al.*<sup>13</sup> reported that people with SCI spent less than 2% of their waking hours engaged in structured exercise or leisure-time physical activity and concluded that physical inactivity is a serious public health issue in this population. Inactivity can lead to further physical deconditioning and ultimately cause a cycle of reduced mobility and increased secondary health conditions.<sup>14</sup> Therefore, there is a need to develop effective implementation strategies for an exercise programme that can promote sustainable behaviour in people with SCI.

The main objective of this pilot study is to evaluate the feasibility and acceptability of a home-based supervised exercise programme and collect preliminary data on the effect of the intervention on physical functioning and quality of life in individuals with chronic SCI. It is hypothesised that targeted physical exercise may promote increased muscle strength of residual musculature, improved trunk stability, enhanced joint mobility and encourage greater participation in daily activities. The results could provide a solid foundation for future larger-scale research on the effectiveness of physical exercise in

individuals with chronic SCI. They could also influence clinical guidelines for the rehabilitation of this population.

## MATERIALS AND METHODS

The study received approval from the Bio-Ethics Committee of the University of Bologna and adhered to the Standard Protocol Items: Recommendations for Interventional Trials reporting guidelines.<sup>15</sup>

### Study design

This is an intervention and prospective pilot study. It will recruit people with chronic SCI. The recruited group will participate in a 3-month exercise home-based programme and receive educational sessions on the importance of maintaining an active lifestyle with SCI. All recruited subjects will be assessed by research staff at baseline, after 6 weeks and after 3 months of adapted physical activity.

### Participant recruitment

The research staff will propose participation in the study to all people with chronic SCI after verifying the presence of inclusion/exclusion criteria. Subsequently, subjects will receive information about the study and be asked to sign the informed consent form. Subjects will be enrolled after signing the informed consent form.

### Inclusion and exclusion procedures

During the baseline assessment, a medical doctor will verify the inclusion/exclusion criteria (table 1) associated with age, diagnosis and comorbid conditions. In contrast, criteria linked to motor function and physical activity will be verified by a researcher in sports science. Personal information (first and last name, address, telephone number(s)) will only be recorded on the informed consent form, together with a study code, if the subject is eligible for the study. Subjects will be identified by their assigned study code on all other forms used in the study.

### Sample size

Power computation has yet to be undertaken for this study as the study design is a feasibility study. The proposed sample size is 15 participants.

### Data collection and measures

The instruments used to collect the primary and secondary outcome measures and the timing of their use are summarised in table 2.

### Primary outcome

The primary outcome will be evaluating adherence to the exercise programme. Adherence will be calculated as the percentage of training sessions completed compared with the total number of scheduled training sessions. As part of the assessment of adherence, the reasons for dropping out of the exercise programme will be investigated.

**Table 1** Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> <li>▶ Diagnosis of paraplegia for at least 5 years</li> <li>▶ Medical certificate for non-competitive activity.</li> <li>▶ Age between 18–70 years.</li> <li>▶ Signed informed consent.</li> <li>▶ Injury level T2 and below.</li> <li>▶ No locomotor activity.</li> <li>▶ Possible passive orthostatic exercise through standing.</li> <li>▶ Possession of an electronic device (tablet and/or pc) with internet access.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Age over 70 years.</li> <li>▶ Severe impairment of communicative and/or sensory functions to the extent that understanding or executing trainer instructions is impossible (dementia, aphasia, blindness, deafness).</li> <li>▶ Heart failure (New York Heart Association class&gt;2).</li> <li>▶ Unstable angina.</li> <li>▶ Lung disease requiring oxygen therapy.</li> <li>▶ Symptomatic peripheral artery disease.</li> <li>▶ Myocardial infarction or hospitalisation within the previous 6 months.</li> <li>▶ Hypertension is poorly controlled with medication (diastolic &gt;95 mm Hg, systolic &gt;160 mm Hg).</li> <li>▶ Relevant neurological conditions compromising motor or cognitive function.</li> <li>▶ Any other condition deemed contraindicated for participation in a mild/moderate-intensity exercise programme by the attending physician (MD).</li> <li>▶ Engagement in structured physical activity.</li> <li>▶ Inability to understand the Italian language.</li> </ul>

### Secondary outcomes

The secondary endpoints will encompass various assessments across various domains, including quality of life, functional capacity, musculoskeletal health and clinical parameters.

Quality of life will be evaluated through modifications in the WHO Quality-of-Life Scale (WHOQOL-BREF) questionnaire, a validated tool used to assess an individual's quality of life across four domains: physical health, psychological health, social relationships, and environment.<sup>16</sup>

Autonomy in self-care and mobility will be measured using relevant subscales of the Spinal Cord Independence Measure III Self-Report.<sup>17</sup>

Psychological well-being and mood will be assessed using the Mental Health Inventory-5, comprising five items that gauge symptoms of depression and anxiety.<sup>18</sup>

Fatigue severity will be gauged through the Fatigue Severity Scale, a questionnaire designed to evaluate the severity and impact of fatigue on daily activities. It encompasses nine items that assess its effects on various aspects of life.<sup>19</sup>

The SCI Secondary Conditions Scale will delve into aspects associated with SCI, including pain, spasticity, and bladder dysfunction.<sup>20</sup>

Sleep quality will be evaluated using the General Sleep Disturbance Scale, which assesses various dimensions of sleep, including quality, latency, and disturbances.<sup>21</sup>

Gastrointestinal dysfunction will be assessed using the Neurogenic Bowel Dysfunction Score, which measures the severity of gastrointestinal issues in individuals with SCI, such as constipation, faecal incontinence and bowel accidents.<sup>22</sup>

Functional capacity will be evaluated through the 6-minute push test, while the range of motion of the upper limbs will be measured with a goniometer.<sup>23</sup>

The push-up test will assess the muscular strength of the upper limbs, and maximal isometric strength will be measured using a handheld dynamometer. The dynamometer measures the peak isometric force generated from a muscle group and is widely used to evaluate the strength of the shoulder.<sup>24</sup>

Trunk control will be evaluated with the Trunk Control Test for SCI, assessing an individual's ability to maintain trunk stability and balance in various positions.<sup>25</sup>

A continuous and non-invasive monitoring device detects physiological parameters, including heart rate, breath frequency, temperature, saturation, posture and movement (ComfTech).

Leisure time physical activity will be quantified using the Leisure Time Physical Activity Questionnaire for People with SCI, tailored specifically for individuals with SCI.<sup>26</sup>

Heart rate during training sessions will be monitored using POLAR heart rate sensor, and participant satisfaction with the physical activity programme will be assessed via a structured questionnaire. It will be verified by a dedicated questionnaire with structured responses based on a 7-point Likert scale.

The reasons for interruption and abandonment will be carefully evaluated during the study.

### Safety

Adverse clinical events (ACEs) that will occur to participants during the study will be carefully recorded. The trainer will record the ACEs that happened during the

**Table 2** Outcome assessment

Socio-demographic parameters			
Date of birth	X		
Gender	X		
Anthropometric parameters			
Weight (kg)	X		
Height (m)	X		
Assessment scales			
Asia scale	X		
Adherence			X
WHOQOL-BREF <sup>16</sup>	X		X
Spinal Cord Independence Measure III Self-Report <sup>17</sup>	X		X
Mental Health Inventory-5 <sup>18</sup>	X	X	X
Fatigue Severity Scale <sup>19</sup>	X	X	X
Spinal Cord Injury Secondary Conditions Scale <sup>20</sup>	X		X
General Sleep Disturbance Scale <sup>21</sup>	X	X	X
Neurogenic bowel dysfunction <sup>22</sup>	X		X
6-minute push up test <sup>23</sup>	X		X
Range of motion with goniometer <sup>33</sup>	X	X	X
Wheelchair push up test <sup>34</sup>	X	X	X
Maximum isometric strength <sup>24</sup>	X	X	X
Trunk Control Test <sup>25</sup>	X		X
Physiological parameters and posture measures using wearable sensors	X		X
Leisure time physical activity questionnaire for people with spinal cord injury <sup>26</sup>	X	X	X
Exercise programme satisfaction			X

WHOQOL-BREF, WHO Quality-of-Life Scale.

exercise sessions at the end of each session. In the case of three consecutive absences, the coordinating centre will contact the participant by telephone to investigate whether the cause of non-attendance at the sessions was an ACE. Based on the records, ACEs will be classified for severity (severe: if the ACE involved hospitalisation/ access to the emergency room; moderate: if the ACE required the intervention of a doctor and/or modification of the usual pharmacological therapy; mild: if the ACE did not require medical intervention and/or modification of the usual pharmacological therapy), place (home: ACE occurred at home; outside: ACE exercise occurred outside the home), and apparatus (apparatus/ system involved).

### Exercise programme

The exercise programme aims to improve joint mobility, muscle strength and trunk stability. The programme is structured into 1-hour sessions, held twice a week for 3 months, conducted online via a dedicated platform under the supervision of highly specialised personnel and in small groups. During each session, heart rate will be monitored using POLAR. Each session is structured into the following sections: warm-up, main part (strength, mobility and proprioception exercises) and cool-down. Only commonly used low-cost tools, such as elastic bands, dumbbells and soft dumbbells, are used during exercise sessions. The trainer will tailor the exercise programme to the needs and preferences of the participants. Subjects will be recommended to perform upper limb bike activities three times a week. The recommended duration of these activities will be 30 min.<sup>27</sup> In this way, subjects will achieve the recommended amount of exercise outlined in the guidelines. Participants are also required to record the performance of these activities in a log.

The protocol includes specific strategies to instruct participants on the correct and safe execution of motor activities, ensuring they are adequately guided throughout the entire programme. Additionally, clear criteria are defined to adjust workload and the number of repetitions, adapting them to each participant's individual functional capacities. This approach aims to ensure proper progression in the exercise programme, maintaining an appropriate and safe level of challenge for each involved individual.

### Statistical analysis

Qualitative variables will be summarised in frequency, while quantitative variables will be summarised in terms of mean and SD (or median and IQR) for the three assessment time points. Friedman's non-parametric analysis of variance for repeated measures will be used to assess the trajectory of scale scores over time (baseline, 6 weeks, 3 months) at a significance level of 0.05. The non-parametric Wilcoxon post-hoc test will also be employed for multiple comparisons: from baseline to 6 weeks and 6 weeks to 3 months, using a significance level of  $p < 0.025$ .

The effect size will be calculated for all scales, adopting Cohen's definitions for interpretation: small=0.20, medium=0.50 and large=0.80. Spearman's correlation ( $\rho$ ) will evaluate potential relationships between demographic factors and outcomes. The strength of the association will be defined as weak for  $\rho < 0.30$ , moderate for  $\rho = 0.30-0.50$  and strong for  $\rho > 0.50$ .

Given that the data will be collected by a research staff of professionals adequately trained in administering questionnaires and tests, we expect a low probability of missing data. However, if it occurs, we plan to use clustering-based imputation. We will use the model to estimate missing values for participants with missing data. This approach involves dividing subjects into clusters, allowing us to estimate missing data using information from other cluster members.



## DISCUSSION

People with SCI face numerous obstacles in adapting to a new life after rehabilitation. Approximately 30% of these individuals are readmitted to a setting of a specialised medical within a year due to injury-related complications such as musculoskeletal, respiratory and skin problems.<sup>28 29</sup> Additionally, individuals with SCIs often lead a sedentary lifestyle, increasing the risk of diseases such as obesity, hypercholesterolaemia, diabetes and heart diseases, thereby reducing life expectancy in this population.<sup>30</sup> Furthermore, individuals with SCI also report lower quality of life compared with non-disabled individuals.<sup>2 3</sup> Many factors influence the quality of life of these individuals, including functional mobility that limits participation in daily activities and work, financial stability, social support, mental health and overall well-being. It is, therefore, essential to offer post-rehabilitation alternatives aimed at improving functionality and positively influencing various aspects of quality of life. However, these individuals have barriers to exercise and/or physical activity, such as a lack of accessible facilities and equipment, financial costs and inadequate exercise guidelines.<sup>31</sup> In this context, promoting participation in physical exercise and ensuring adequate access to overcome these challenges is crucial. Exercise programmes that directly address these obstacles aim to fill the gaps in post-rehabilitation care within the healthcare system.<sup>32</sup> In doing so, they create a supportive environment that promotes physical well-being and full participation in the daily lives of those facing chronic SCIs. The relevance of issues related to this condition and its consequences on functional aspects and social participation makes it necessary to adopt a comprehensive approach to individuals with SCI. This requires personalised and specific assessment and treatment plans to meet each person's diverse and specific needs. A multidisciplinary team of professionals should support patients with SCI, including an expert in Physical and Rehabilitation Medicine, a graduate in physiotherapy and a master's degree holder in preventive and adapted physical activity sciences and techniques.

Several limitations of this protocol merit consideration as they could affect the interpretation of the study results. Notably, the absence of a control group engaging in sham or no activities warrants attention. However, it is important to emphasise that the primary focus of the study is to assess the feasibility of a home-based physical exercise programme for individuals with SCIs. Consequently, while we cannot empirically demonstrate the effectiveness of the administered exercise programme, the study aims to provide valuable insights into its feasibility and potential benefits in a real-world setting. Moreover, the heterogeneity of the group, potentially comprising individuals with various comorbidities reflective of the reference population, could be a limitation in interpreting the collected data. Additionally, the study's duration may limit our ability to observe the long-term effects and sustainability of the exercise programme. Furthermore, the small sample size

and potential participant dropout could introduce bias and affect the generalisability of the results.

## CONCLUSION

While guidelines for individuals with SCI prevention advocate regular exercise, many encounter challenges in adhering to these recommendations, likely due to a lack of resources. The results of this study could be relevant for future indications of the best setting and strategy to ensure adherence to physical activity and add to the current evidence base for clinicians, exercise trainers and policy-makers.

## Research ethics and dissemination

The study processes will follow the study protocol, and any protocol amendments will be submitted to the University of Bologna Bioethics Committee. All documents will be kept confidential. The study protocol will be published in an academic journal. The study results will be disseminated via conference presentations, reports to the grant funder, websites or social media and publications in peer-reviewed journals. The presentation of the study will keep the anonymity of participants.

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**Patient consent for publication** Not applicable.

**Ethics approval** The local bio-ethical committee approved this study protocol in April 2024 Prot. N. 0101085. Participants gave informed consent to participate in the study before taking part.

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**Data availability statement** Data sharing not applicable as no datasets generated and/or analysed for this study.

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