ISRCTN19102055 https://doi.org/10.1186/ISRCTN19102055

Robotics- and AI-based hospital and home rehabilitation for children with spinal cord injury

Submission date
29/10/2025

Recruitment status
Recruiting

Registration date
29/10/2025

Overall study status
Ongoing

Last Edited
29/10/2025

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
This study explores how assistive social robotics and artificial intelligence can enhance rehabilitation for children with spinal cord injury. The goal is to assess the usability, satisfaction, and effectiveness of the INROBICS platform - a robotic system designed to support physical therapy both in hospital and at home.

Who can participate?
Children aged 7–16 years with spinal cord injury below the C6 level, who are clinically stable and can sit independently, will be invited to participate. Participants must have parental consent.

What does the study involve?
Participants will be randomly assigned to one of two groups. The intervention group will complete 15 rehabilitation sessions using the INROBICS robot at the hospital and 15 sessions at home using the virtual version. The control group will receive 30 conventional therapy sessions. Each session includes warm-up, main exercise, and cool-down phases. Assessments will be performed before, during, and after treatment, and again three months later.

What are the possible benefits and risks of participating?
The Inrobics Rehab system may improve rehabilitation engagement, motor recovery, and emotional wellbeing. Risks are minimal and similar to standard therapy; sessions are supervised by rehabilitation professionals.

Where is the study run from?
The study is conducted at the Hospital Nacional de Parapléjicos (Toledo, Spain) in collaboration with Inrobics Social Robotics, S.L.

When is the study starting and how long is it expected to run for?
March 2024 to February 2027

Who is funding the study?
The study is funded by the Ministry of Science, Innovation and Universities (Spain), under the Public–Private Collaboration Programme 2023

Who is the main contact?
Dr Ana de los Reyes Guzmán, adlos@sescam.jccm.es

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Mrs Ana De los Reyes

Contact details
FINCA DE, Carr. de la Peraleda S/N
Toledo
Spain
45004
+34 (0)925247700
adlos@sescam.jccm.es

Type(s)
Public

Contact name
Mrs Fuensanta García

ORCID ID
https://orcid.org/0009-0003-5104-0491

Contact details
Av. Gregorio Peces Barba 1
Madrid
Spain
28919
+34 (0)630423231
fgarcia@inrobics.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2263

Study information

Scientific Title
Hospital and home rehabilitation based on social assistive robotics and artificial intelligence for paediatric patients

Study objectives
The general objective of the study is to analyse the user experience, usability and effectiveness of the Inrobics Rehab platform based on Social Assistance Robotics and Artificial Intelligence.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/09/2025, Ethics Committee for Clinical Research with Medicines at the Toledo University Hospital Complex (Av. del Río Guadiana, Toledo, 45007, Spain; +34 (0)925269200 extension: 48557; ceic-chto-secretario@sescam.jccm.es), ref: 2263

Study design
Clinical, analytical, experimental, prospective, randomized controlled study

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Paediatric school patients aged between 7 and 16 years with subacute or chronic spinal cord injury

Interventions
Participants will be randomly assigned to either the intervention group or the control group using a simple randomisation technique. A computer-generated list of random numbers will determine treatment allocation, which will be concealed in sequentially numbered, sealed envelopes. Each participant receives the envelope in order of enrolment, revealing assignment to either the INROBICS intervention group or the control group.

1. Intervention group: each participant will complete 15 sessions with the INROBICS Clinic platform and 15 with INROBICS Virtual spread over 4 weeks.
2. Control group: each participant will receive 30 experimental sessions of conventional therapy over 4 weeks.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Inrobics Rehab

Primary outcome(s)

Assessments are conducted at four timepoints: T0 (baseline evaluation), T1 (post-clinical intervention), T2 (post-virtual intervention), and T3 (3-month follow-up)

Efficacy Measures:
1. PENN Spasm Frequency Scale: Assesses the frequency and severity of muscle spasms, providing a quantitative evaluation of spasticity (T0)
2. Electronic Spinal Cord Independence Measure (e-SCIM-III): Evaluates functional independence in patients with spinal cord injury (SCI) (T0, T1, T2, T3)

Emotional State:
1. Children's Depression Inventory (CDI): Administered to participants under 16 years of age (T0, T1, T2, T3)
2. State-Trait Anxiety Inventory for Children (STAIC): Administered to participants aged 9–15 years (T0, T1, T2, T3)

Perceived Health and Mental Workload:
1. EQoL-5D-Y5L: Assesses perceived quality of life. (T0, T1, T2, T3)
2. Pain (VAS): Pain intensity is measured using the Visual Analogue Scale with emoticons suitable for children and adolescents (T0, T1, T2, T3)
3. NASA-TLX: Evaluates perceived mental workload and fatigue associated with the training tasks (T1, T2)

Cognitive Scales:
1. Digit Span (WISC-V subtest): Evaluates attention and working memory in participants under 16 years (T0, T1, T2, T3)
2. Face Perception Test: Assesses perceptual and attentional skills in participants under 16 years (T0, T1, T2, T3)
3. Executive Function Inventory (EFI): Completed by parents for children over 6 years to assess executive functioning in daily life (T0, T1, T2, T3)

Functional Scales:
1. Edinburgh Handedness Inventory: Determines hand dominance in participants over 3 years (T0)
2. Box and Block Test: Assesses gross manual dexterity in participants over 6 years (T0, T1, T2, T3)
3. Jebsen–Taylor Hand Function Test: Evaluates hand function and coordination in participants over 6 years (T0, T1, T2, T3)

Motor Assessment:
1. Upper Limb Kinematic Evaluation: Quantifies movement precision and quality during activities of daily living (ADLs) using the assistive social robotics system (see Annex 3) (T0, T2, T3)

Key secondary outcome(s))

Assessments are conducted at four timepoints: T0 (baseline evaluation), T1 (post-clinical intervention), T2 (post-virtual intervention), and T3 (3-month follow-up)

Usability Measures:
1. QUEST 2.0 (Quebec User Evaluation of Satisfaction with Assistive Technology): Assesses user satisfaction with the assistive device (T1, T2)
2. IPAQ Questionnaire: Measures time spent performing different physical activities in children and adolescents (T0, T1, T2, T3)
3. Hopkins Scale: Evaluates engagement in the training program for both adult and paediatric participants (T1, T2)

Device-Recorded Parameters:
1. All kinematic and physiological parameters are recorded using the Inrobics Rehab system and R software (version 4.3.1 for Ubuntu)
2. Range of Motion: Goniometric data capturing joint mobility (T1, T2)
3. Accuracy Rate: Quantifies successful task completion (T1, T2)
4. Trunk and Neck Deviation: Monitors postural deviations during training (T1, T2)
5. % Heart Rate Reserve (%HRR): Determines exercise intensity during sessions (T1, T2)
6. Motor Precision: Assesses the accuracy of reproduced target postures (T1, T2)
7. Reaction Time: Measures the latency between stimulus onset and movement initiation (T1, T2)
8. Engagement: Indicates the level of active participation throughout the task (T1, T2)
9. Performance by Activity Type: Evaluates execution across different motor games (e.g., dance, don't stop, symbolic), combining metrics such as reaction time, memory rate, accuracy rate, learning rate, and execution speed (T1, T2)

User Satisfaction:
1. Self-Assessment Manikin (SAM): A pictorial, non-verbal scale assessing pleasure, arousal, and dominance associated with affective responses to stimuli (T1, T2)

Completion date
28/02/2027

Eligibility

Key inclusion criteria
1. Aged between 7 and 16 years old
2. Clinically stable
3. Diagnosis of spinal cord injury below C6 in cases of AIS (ASIA Impairment Scale) severity A or B, or any level of incomplete spinal cord injury that allows reach with the upper limbs
4. Independent sitting (including technical aids such as belts, wedges, trunk supports, etc)
5. Parents, guardians or family members must have signed the corresponding informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
7 years

Upper age limit
16 years

Sex
All

Key exclusion criteria
1. Unstable orthopaedic injuries such as unconsolidated fractures or unstable osteosynthesis systems in the upper limbs
2. Suffering from severe pain, joint stiffness and/or severe spasticity in the upper limbs
3. Severe bronchopneumopathy and/or heart disease requiring monitoring during exercise or a history of abnormal response to physical exertion prior to spinal cord injury
4. Severe visual impairments, cognitive impairment and/or incapacitating psychiatric illness

Date of first enrolment
01/11/2025

Date of final enrolment
02/02/2027

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Nacional de Parapléjicos
FINCA DE, Carr. de la Peraleda S/N
Toledo
Spain
45004

Sponsor information

Organisation
Inrobics Social Robotics, S.L.

Funder(s)

Funder type
Industry

Funder Name
Inrobics Social Robotics, S.L.

Funder Name

Agencia Estatal de Investigación

Alternative Name(s)
Spanish State Research Agency, Spanish Agencia Estatal de Investigación, AEI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Funder Name
Ministerio de Ciencia, Innovación y Universidades

Alternative Name(s)
Ministry of Science, Innovation and Universities, MCIU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan
Data sharing plans for the current study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			29/10/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes