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Using robot-assisted training to support action sequencing and autonomy in children with neurodevelopmental conditions

Submission date
12/08/2025

Recruitment status
No longer recruiting

Registration date
06/11/2025

Overall study status
Completed

Last Edited
06/11/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Children with Autism Spectrum Disorder (ASD) often find it difficult to carry out everyday routines and to understand the thoughts and feelings of others. These skills are essential for developing independence and confidence, but they can be hard to practice in traditional therapy, which may lack consistency and engagement. This study investigates whether training with a humanoid robot, called iCub, can support children with ASD in learning and practising such skills. The robot is used as a training partner in structured activities, such as brushing teeth, preparing a school bag, or role-playing social situations like visiting a shop. The aim is to determine whether robot-assisted training can strengthen children's ability to remember and carry out sequences of actions and to engage more effectively in social interactions, thereby laying the foundations for greater autonomy in daily life.

Who can participate?
The study is open to children between the ages of 6 and 15 years who have a clinical diagnosis of Autism Spectrum Disorder. Participation is voluntary and requires informed consent from parents or legal guardians.

What does the study involve?
The research is organised as a randomised two-period crossover trial. This means that each child takes part in two phases, one involving robot-assisted training and the other without such training, so that comparisons can be made between the two conditions. In the robot-assisted phase, the iCub robot guides the child through structured routines and role-playing exercises, helping them to practise step by step. In the control phase, children do not interact with the robot, providing a baseline for comparison. Each child attends two individual sessions per week, lasting about 45 minutes each, over several weeks. A short break between phases ensures that the effects of one condition do not carry over into the other. Progress is assessed at three moments: before the training begins, after the first phase, and after the crossover is complete. All activities are conducted in a clinical setting under the supervision of therapists and researchers.

What are the possible benefits and risks of participating?
By taking part, children may benefit from improved memory for action sequences, stronger social skills, and greater independence in daily activities. These gains could make everyday life easier both for the children and their families. The study involves very little risk. Some children might experience temporary frustration, fatigue, or loss of interest if tasks feel too repetitive or challenging. To prevent this, sessions are carefully monitored by therapists, and children are free to stop at any time if they feel uncomfortable.

Where is the study run from?
The research is coordinated by the Italian Institute of Technology (Istituto Italiano di Tecnologia, IIT) in Genoa, Italy. It is carried out in collaboration with Opera Don Orione healthcare centres and other specialist facilities for children with autism in the same region.

When is the study starting and how long is it expected to run for?
June 2024 to September 2025

Who is funding the study?
The project is funded by the European Research Council through the Proof of Concept grant 2023, reference ERC-2023-PoC-101155938, and by the Italian Institute of Technology (IIT).

Who is the main contact?
The principal investigator of the study is Professor Agnieszka Wykowska at the Italian Institute of Technology in Genoa, who can be contacted at agnieszka.wykowska@iit.it. The scientific contact for the study is Dr Davide Ghiglino, also based at the Italian Institute of Technology, who can be reached at davide.ghiglino@outlook.it.

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ERC-2023-POC-101155938

Study information

Scientific Title
Enhancing adaptive behavior in children with autism through robot-guided action sequencing: the RONIN proof-of-concept study

Acronym
RONIN_Phase1

Study objectives
The RONIN project aims to evaluate whether robot-assisted training can enhance the ability of children with neurodevelopmental conditions, particularly Autism Spectrum Disorder (ASD), to understand, remember, and generate sequences of goal-directed actions. These skills are considered foundational for achieving greater autonomy in everyday life.

Specifically, the study will:
1. Assess the effectiveness of robot-assisted interventions (delivered via a humanoid robot) in improving action sequencing skills related to either daily routines or socially embedded tasks.
2. Compare outcomes across two training conditions:
2.1. A self-care-focused condition (e.g., brushing teeth, dressing)
2.2. A social-routines-focused condition (e.g., navigating public spaces, visiting a dentist)
3. Evaluate differences between robot-assisted and no-training control phases using a randomized crossover design.
4. Explore whether training improvements generalize over time and differ depending on the nature of the stimuli (daily vs social tasks).
5. Gather clinician feedback via focus groups to iteratively refine the robot-assisted protocol and assess its potential integration in therapeutic contexts.

The ultimate goal is to determine whether robot-mediated interaction can serve as a reliable and scalable tool for supporting cognitive and behavioral development in children with ASD.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/06/2024, Comitato Etico Territoriale Liguria (Piazza della Vittoria 15, terzo piano, Genova, 16121, Italy; +39 (0)10 548 8242; CETLiguria@alisa.liguria.it), ref: 213/2018 - DB id 4125

Study design
Randomized two-period crossover study

Primary study design
Interventional

Study type(s)
Efficacy, Quality of life, Safety, Treatment

Health condition(s) or problem(s) studied
Autism spectrum disorder (ASD)

Interventions
The study evaluates the effectiveness of a robot-assisted behavioral intervention aimed at improving action sequencing skills in children with Autism Spectrum Disorder (ASD). The intervention is compared with a no-training control phase in a randomized crossover design.

Children with ASD often struggle to understand and generate sequences of actions needed for independent functioning. The intervention uses a humanoid robot (iCub) to provide structured, consistent, and engaging training in building and recalling goal-directed sequences. The hypothesis is that such interaction can strengthen cognitive prerequisites for autonomy.

Participants are randomly assigned to one of two groups:
Group A receives a robot-assisted training focused on daily self-care routines (e.g., brushing teeth, dressing).
Group B receives a robot-assisted training focused on social routines (e.g., visiting public places, interacting in social settings).

The crossover structure allows each group to serve as the control for the other. Initially, Group B acts as a control for Group A’s training phase. After a 1–2-week washout period, Group B receives their training, enabling within-group and between-group comparisons.

Interventions are delivered through a humanoid robot in structured clinical sessions. Children interact with the robot to collaboratively build action sequences.
Each session lasts approximately 45 minutes, with two sessions per week over several weeks.
Each training phase lasts 4–5 weeks

The design supports both interventional and observational analyses of how robotic training impacts children’s ability to sequence actions relevant to autonomy and adaptive functioning.

Training stimuli:
1. Self-care routines (e.g., brushing teeth, dressing)
2. Social routines (e.g., taking a bus, visiting a cinema)
3. Visual aids and verbal cues support memory and comprehension

Children build action sequences in collaboration with the robot. Sessions are conducted face-to-face in structured settings. Each group undergoes one training phase and one control phase (crossover design). Tasks are designed to replicate real-life scenarios. Robot-assisted sessions are monitored by researchers specialized in social cognition and HRI. Clinical supervision is provided by therapists experienced in ASD. Individual sessions, face-to-face, are delivered in controlled clinical environments resembling real-world settings at clinical centers in Genova, Italy, including specialized pediatric and ASD-focused facilities.

Scenarios are adjusted in complexity and content based on the child's engagement and progress. Visual/verbal cues are adapted to individual comprehension levels. Minor real-time adjustments (e.g., robot's timing or feedback) were made to maximize child engagement and minimize frustration. No major deviations from the protocol occurred. All sessions followed standardized protocols. Session fidelity was ensured by video recordings reviewed by independent evaluators.

Outcome assessments are conducted at three timepoints:
T0 (Baseline): Before any training
T1 (Midpoint): After the first training phase
T2 (Post-crossover): After the second training phase

Intervention Type
Behavioural

Primary outcome(s)
Action sequencing and adaptive functioning:
1. Theory of Mind, facial affect recognition, and contextual understanding of social interactions, assessed using NEPSY-II – Social Perception Subscale
2. Ability to comprehend, recall, and execute sequential actions in both cognitive and practical domains, assessed using Batteria per la Valutazione della Sequenzialità Cognitiva e Operativa (BVSCO)
3. Practical, social, and conceptual skills essential for daily functioning and autonomy in real-life contexts, assessed using the Adaptive Behavior Assessment System (ABAS)

Assessment Timeline:
T0 (Baseline) – Before any intervention
T1 (Midpoint) – After the first phase (training or control)
T2 (Post-crossover) – After the second phase

Blinding:
All assessments are conducted by clinicians blind to the intervention phase of the participant to reduce bias.

Scoring and Interpretation:
Improvement is quantified through pre-post differences across all three tools, focusing on gains in social cognition, sequencing ability, and adaptive functioning. Statistical comparisons are made across and within groups (crossover design).

Key secondary outcome(s))

Clinician feedback via focus groups: structured focus groups were conducted with clinical professionals at three key time points during the study: 17 July 2024, 15 January 2025, and 21 May 2025. These sessions served as both a participatory research method and a tool to assess the clinical relevance, usability, and perceived effectiveness of the robot-assisted intervention.

Assessment Focus:
1. Observed changes in children's autonomy and behavior in clinical settings
2. Perceived generalization of training effects to daily life
3. Suggestions for improving training protocols and personalization
4. Practical feasibility of long-term implementation

Analysis Method:
Qualitative content analysis of transcribed focus group discussions, coded for themes such as engagement, skill transfer, adaptability, and clinical utility.

Purpose:
These qualitative insights support the interpretation of quantitative outcomes and guide the iterative development of the RONIN intervention for future clinical trials.

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Children aged 6 to 15 years at the time of enrollment
2. Formal diagnosis of Autism Spectrum Disorder (ASD) confirmed through standardized tools:
2.1. Autism Diagnostic Interview–Revised (ADI-R)
2.2. Autism Diagnostic Observation Schedule – Second Edition (ADOS-2)
3. Sufficient receptive language and cognitive ability to understand and follow task instructions
4. Regular attendance at the participating clinical center(s)
5. Parental or legal guardian consent obtained, with age-appropriate assent from the child
6. Inclusive of all genders, ethnicities, and socioeconomic backgrounds
7. Not currently enrolled in any conflicting experimental therapy programs

Participant type(s)
Health professional, Patient, Service user

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
15 years

Sex

All

Total final enrolment
62

Key exclusion criteria
1. Presence of severe intellectual disability that would prevent meaningful engagement with the training protocol
2. Significant behavioral disturbances (e.g., severe aggression, self-injury) that could interfere with participation or safety
3. Uncorrected sensory impairments (e.g., vision or hearing problems) that would limit interaction with the robot or materials
4. Diagnosed neurological or medical conditions not related to ASD that may confound outcomes
5. Ongoing participation in other experimental or non-standardized interventions
6. Irregular attendance at the clinical center, preventing completion of the training protocol or assessments
7. Inability to obtain informed consent from a parent or legal guardian

Date of first enrolment
18/09/2024

Date of final enrolment
17/02/2025

Locations

Countries of recruitment
Italy

Study participating centre
Istituto Paverano – Centro Boggiano Pico
Via Benvenuto Cellini 22
Genova
Italy
16143

Sponsor information

Organisation
Istituto Italiano di Tecnologia

Funder(s)

Funder type

Research council

Funder Name
European Research Council

Alternative Name(s)
The European Research Council, ERC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The study team intends to share anonymized, GDPR-compliant individual participant data once the full analysis is complete and the final dataset has been prepared.

The shared data will include:
1. Processed behavioral and psychometric outcome measures
2. Associated metadata and documentation
3. Analysis scripts and relevant codebooks

Data will be made accessible via publicly available repositories such as the Open Science Framework (OSF) and/or the IIT Dataverse. Access will be open, with appropriate citations and data use guidelines provided.

No identifiable personal data will be included, and all shared materials will comply with relevant ethical and legal standards.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 4	18/03/2024	19/08/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes