

# Using robots-assisted training to boost social skills in children with autism

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 06/05/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/07/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input checked="" type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

This study explores whether a humanoid robot, iCub, can help children with Autism Spectrum Disorder (ASD) improve social skills like understanding others' thoughts and feelings (Theory of Mind). The goal is to see if robots can support traditional therapy and make learning social skills easier.

### Who can participate?

Children aged 5 to 9 years old with an ASD diagnosis

### What does the study involve?

Participants take part in both robot-assisted and human-assisted therapy using role-playing games. Their progress is measured by experts who don't know which training they received.

### What are the possible benefits and risks of participating?

The study is safe and engaging, with the hope of creating better therapy methods for children with developmental conditions.

The possible risks of participating in the study are minimal, as the intervention follows a structured, evidence-based approach designed to be safe and beneficial for children with ASD. However, potential risks include mild discomfort or frustration during therapy sessions, especially if a child struggles with engagement or transitions between activities. Additionally, some children may experience fatigue or loss of interest due to the structured nature of the training. To mitigate these risks, the sessions are carefully monitored by experienced clinicians, and children can withdraw at any time if they show signs of distress or discomfort. The study also ensures ethical safeguards, including informed consent and continuous assessment of participant well-being.

### Where is the study run from?

The Italian Institute of Technology (Istituto Italiano di Tecnologia) (IIT) and Opera Don Orione healthcare centers, Italy

When is the study starting and how long is it expected to run for?  
January 2018 to December 2028

Who is funding the study?  
1. Italian Institute of Technology (IIT)  
2. European Research Council (ERC)

Who is the main contact?  
Prof Agnieszka Wykowska, [agnieszka.wykowska@iit.it](mailto:agnieszka.wykowska@iit.it)

## Contact information

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

S4ASD001

## **Study information**

**Scientific Title**

Simulating social cognition: a randomized controlled trial of a humanoid-based approach to improve theory of mind skills in autism

**Study objectives**

The study hypothesizes that robot-assisted training using the humanoid robot iCub will significantly improve Theory of Mind (ToM) skills in children with Autism Spectrum Disorder (ASD) compared to both traditional therapy and human-assisted control conditions. The hypothesis further suggests that the robot's predictable, engaging, and interactive features will uniquely contribute to social cognition development, leading to improvements that are not observed in human-led interventions.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 06/11/2018, Territorial Ethics Committee (CET) Liguria (Comitato etico territoriale (CET) Liguria) (c/o A.Li.Sa. Piazza della Vittoria 15, terzo piano, Genova, 16121, Italy; +390105488242; CETLiguria@alisa.liguria.it), ref: N. CET - Liguria: 213/2018

**Study design**

Randomized multicentric two-period crossover trial

**Primary study design**

Interventional

**Secondary study design**

Randomised cross over trial

**Study setting(s)**

Childcare/pre-school, Community, Other therapist office

**Study type(s)**

Treatment, Efficacy

**Participant information sheet**

See study outputs table

**Health condition(s) or problem(s) studied**

Neurodevelopmental disorders, specifically Autism Spectrum Disorder (ASD), with a focus on social cognition and Theory of Mind (ToM) interventions.

## **Interventions**

The study follows a two-period crossover design to compare the effectiveness of robot-assisted therapy and traditional therapy in improving Theory of Mind (ToM) skills in children with Autism Spectrum Disorder (ASD). The research takes place in multiple clinical centers in Genova, Italy, and is part of a broader ethical approval that covers multiple studies sharing the same crossover structure and clinical population.

### **1. Brief Name**

- The intervention is called robot-assisted social cognition training for children with ASD, implemented using the humanoid robot iCub.

### **2. Why – Rationale and Goal**

- The intervention is based on the Theory of Mind (ToM) framework, which refers to the ability to attribute mental states (beliefs, intentions, and emotions) to oneself and others. Children with ASD often struggle with these skills, leading to challenges in social interactions. Traditional therapy uses human-assisted role-playing, but it can lack consistency. Robot-assisted therapy offers predictable, engaging, and structured interactions, making it a promising tool for improving ToM skills.

### **3. What – Materials Used**

- The key component of the intervention is the humanoid robot iCub, which provides structured social interactions through programmed role-playing scenarios. These include activities like ordering at a café, taking turns in conversation, and recognizing social cues. The sessions incorporate visual and verbal feedback from the robot. In traditional therapy, human therapists guide children through similar exercises, without the use of robotics.

### **4. Procedures – Description of the Intervention**

- Children participate in two intervention types:

Robot-assisted training: The iCub robot engages children in structured social role-plays, where it demonstrates social behaviors (e.g., making requests, responding to emotions, turn-taking). Children practice these skills under clinical supervision, ensuring structured feedback and reinforcement.

Traditional therapy (control condition): The same ToM skills are taught by human therapists, following an identical structure to the robot-assisted intervention but without robotic facilitation.

Active control condition: A trained clinician mimics the robot's behaviors, ensuring that improvements are due to the robot itself, not just the intervention structure.

### **5. Who Provided the Intervention**

- Therapy sessions are conducted by licensed clinical psychologists and therapists specializing in ASD and Applied Behavior Analysis (ABA). Robot-assisted training is programmed and monitored by researchers in social cognition and human-robot interaction.

### **6. How – Mode of Delivery**

- The intervention is delivered face-to-face in a structured clinical setting. Sessions are conducted individually, with the child interacting directly with the robot or therapist, guided by clinical supervisors.

## 7. Where – Location and Setting

- The study is conducted in clinical centers across Genova, Italy, including specialized facilities for ASD interventions. The therapy rooms are designed to simulate real-life social environments (e.g., a mini café setup), creating an ecologically valid learning experience.

## 8. When and How Much – Duration and Frequency

- Each child undergoes:

Two therapy sessions per week

Each session lasts approximately 45 minutes

Total duration: 8 weeks (including both robot-assisted and traditional therapy conditions)

Assessments at three points: before therapy (T0), after the first intervention phase (T1), and after crossover (T2).

A brief wash-out period (1-2 weeks) is included between the two conditions to minimize carryover effects.

## 9. Tailoring – Personalization of the Intervention

- While the intervention follows a structured protocol, difficulty levels are adjusted based on the child's progress. The robot's responses and scenarios can be personalized to match the child's engagement and comprehension levels.

## 10. Modifications – Changes During the Study

- No major modifications were made during the study. However, minor adjustments (e.g., adapting the robot's prompts for specific children) were implemented to ensure effective engagement.

## 11. How Well – Adherence and Fidelity

- Planned fidelity measures: Therapists and researchers ensured that intervention sessions were delivered consistently by following structured protocols. Actual fidelity: Sessions were video-recorded and reviewed by independent evaluators to verify that the intervention was delivered as planned.

## Intervention Type

Behavioural

## Primary outcome measure

Theory of Mind (ToM) improvements measured using the NEPSY-II Social Perception subscale at T0 (Baseline), T1 (Midpoint) and T2 (Final)

In this crossover design, participants experience both interventions, ensuring direct comparisons:

T0 (Baseline): Measures ToM skills before any therapy

T1 (Midpoint): After approximately 8 weeks of either robot-assisted or traditional therapy, ToM skills are reassessed, then the groups switch interventions with a 1-2 week wash-out to prevent carryover effects.

T2 (Final): After the second therapy phase, a final assessment determines whether gains persisted and if additional improvements occurred

## Secondary outcome measures

There are no secondary outcome measures

## Overall study start date

02/01/2018

**Completion date**

15/12/2028

## Eligibility

**Key inclusion criteria**

1. Participants included children aged 5 to 9 years with a formal diagnosis of Autism Spectrum Disorder (ASD).
2. Diagnosis was confirmed through the Autism Diagnostic Interview-Revised (ADI-R) and the Autism Diagnostic Observation Schedule - Second Edition (ADOS-2).
3. Participants were required to have the ability to understand game instructions to ensure meaningful engagement in the intervention.
4. Participants were selected from those regularly attending the clinical center for ongoing therapy.
5. Inclusion was non-discriminatory, ensuring broad representation regardless of race, ethnicity, culture, gender, or socioeconomic status.
6. All participants had parental or legal guardian consent.

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

5 Years

**Upper age limit**

9 Years

**Sex**

Both

**Target number of participants**

46

**Total final enrolment**

46

**Key exclusion criteria**

1. Severe intellectual disabilities
2. Significant behavioral disturbances
3. Uncorrected sensory impairments
4. Medical or neurological conditions unrelated to ASD
5. Concurrent experimental therapies
6. Inconsistent attendance at the clinical center

**Date of first enrolment**

02/01/2019

**Date of final enrolment**

15/12/2023

## **Locations**

**Countries of recruitment**

Italy

**Study participating centre**

**Istituto Paverano Centro Boggiano Pico**

Via Benvenuto Cellini

Genova

Italy

16143

**Study participating centre**

**PHILOS Accademia Pedagogica**

Via Caffaro, 10

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16124

## **Sponsor information**

**Organisation**

Italian Institute of Technology

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**Sponsor type**

Research organisation

**Website**

<https://www.iit.it/it/home>

**ROR**

<https://ror.org/042t93s57>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Istituto Italiano di Tecnologia

## Alternative Name(s)

Italian Institute of Technology, IIT at Sapienz, IIT@Sapienz, IIT

## Funding Body Type

Government organisation

## Funding Body Subtype

Local government

## Location

Italy

## Funder Name

Ministero dell'Università e della Ricerca

## Alternative Name(s)

Ministry for Universities and Research, Italy, Ministry for Universities and Research, Ministero Università e Ricerca, Italian Ministero Università e Ricerca, MUR, M.U.R.

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

Italy

## Funder Name

European Research Council

## Alternative Name(s)

ERC

## Funding Body Type



Government organisation

Funding Body Subtype  
National government

Location

## Results and Publications

### Publication and dissemination plan

The publication and dissemination plan follows ethical guidelines, ensuring results are shared through peer-reviewed international journals in cognitive science, clinical psychology, and robotics. Findings will also be presented at major conferences in psychology, neuroscience, and assistive technology. To engage healthcare professionals, educators, and families of children with ASD, results will be shared through workshops, outreach events, and professional training programs. Lay summaries will be provided to ensure accessibility for non-specialist audiences, including policymakers and advocacy groups.

Intention to publish date  
01/03/2025

### Individual participant data (IPD) sharing plan

The participant-level data (individual participant data, IPD) collected during the study includes raw behavioral and psychometric measures, but due to GDPR and ethical guidelines, these raw data cannot be stored or shared as they are linked to participant IDs. However, the processed dataset used for analysis, along with the analysis scripts, is publicly available at Open Science Framework (OSF) under the DOI 10.17605/OSF.IO/6DCRA. The dataset and scripts can be accessed at <https://osf.io/6dcra/>.

IPD sharing plan summary  
Stored in publicly available repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Dataset</a>		13/10/2024	26/02/2025	No	No
<a href="#">Participant information sheet</a>	version 04	18/03/2024	05/03/2025	No	Yes
<a href="#">Participant information sheet</a>	version 03	01/06/2021	05/03/2025	No	Yes
<a href="#">Results article</a>		29/07/2025	30/07/2025	Yes	No