ISRCTN15341724 https://doi.org/10.1186/ISRCTN15341724

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

Submission date
25/02/2025

Recruitment status
No longer recruiting

Registration date
06/05/2025

Overall study status
Ongoing

Last Edited
30/07/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[X] 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

Contact information

Type(s)
Public, Principal investigator

Contact name
Prof Agnieszka Wykowska

ORCID ID
https://orcid.org/0000-0003-3323-7357

Contact details
Via Enrico Melen, 83
Genoa
Italy
16152
+390102897242
agnieszka.wykowska@iit.it

Type(s)
Scientific

Contact name
Dr Davide Ghiglino

ORCID ID
https://orcid.org/0000-0002-7825-732X

Contact details
Via Ferrara 215 int. 24
Genova
Italy
16127
+393452268583
davide.ghiglino@outlook.it

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment, Efficacy

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(s)
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

Key secondary outcome(s))
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
9 years

Sex
All

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

Genova
Italy
16124

Sponsor information

Organisation
Italian Institute of Technology

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, MUR Ministero dell'Università e della Ricerca, 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)
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 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?
Results article		29/07/2025	30/07/2025	Yes	No
Dataset		13/10/2024	26/02/2025	No	No
Participant information sheet	version 04	18/03/2024	05/03/2025	No	Yes
Participant information sheet	version 03	01/06/2021	05/03/2025	No	Yes