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Social robots as tools in special education (SRTSE)

Submission date	Recruitment status	[_] Prospectively registered
09/02/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/03/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/12/2022	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Autism spectrum disorder (ASD) is a condition related to brain development that impacts how a person perceives and socializes with others, causing problems in social interaction and communication.
Integrating a social-humanoid robot within the standard clinical treatment has been proven promising in caring for children with ASD and in providing clinicians means to connect with ASD children in an easier way. Recent research also highlights the fact that children with ASD are attracted to robots, possibly because they seem to adjust better to interacting with the robot's predictable and repeated mode of action.
This study is focused on evaluating the effect of a robot-assisted psychosocial intervention for children with autism spectrum disorders.

Who can participate?
Children aged 6–12 years with a confirmed ASD diagnosis, along with their parents.

What does the study involve?
The study involves pediatric assessment, neuropsychological testing and psychometric evaluation. Parents are involved by providing a complete medical and psychosocial history and completing questionnaires to monitor the child's social and practical functioning. Similar questionnaires are given to the child's teachers. The intervention emphasizes interaction through activities and games of emotion recognition, self-regulation, imitation, shared attention, memory, sequences and social scenarios.

What are the possible benefits and risks of participating?
Possible benefits are improvement in socio-emotional functioning. Participation in the protocol cannot have any negative consequences for the participants. In the unlikely event that a child experiences any discomfort in the assessment or intervention session, the reasons for discomfort will be investigated and only if it is deemed completely safe will the child be allowed to continue at a later date, otherwise and if necessary, participation will be discontinued and you will receive the necessary information and guidance.

Where is the study run from?
The research protocol is implemented at the 4th Pediatric Clinic of the Aristotle University of Thessaloniki, Papageorgiou General Hospital and at the "Praxis" Center in Kavala (Greece)

When is the study starting and how long is it expected to run for?
June 2018 to June 2022

Who is funding the study?
Funded from: Action “RESEARCH – DEVELOP - INNOVATE”, cycle A, Intervention II, Operational Programme “Competitiveness, Entrepreneurship and Innovation”, NSRF (National Strategic Reference Framework) of Greece 2014-2020 Project no. T1EDK-00929

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
T1EDK-00929

Study information

Scientific Title

Effectiveness of a robot-assisted psychological intervention designed to help children with Autism Spectrum Disorder improve their socio-emotional skills.

Acronym
SRTSE

Study objectives
This study is focused at evaluating the efficacy of a robot-assisted psychosocial intervention for children with autism spectrum disorders. The secondary goal is to explore potential differences between a robot- assisted intervention group and a control group that receives intervention by humans only. Specifically, the main hypothesis is that children in both groups at the end of the intervention will achieve improvements in social perception, prosocial behaviour and emotion regulation. The secondary hypothesis is that children in the robot-assisted group will have similar improvements compared to the children engaged in the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/10/2018, Papageorgiou General Hospital scientific committee (Periferiaki Odos, N. Eykarpita, Thessaloniki, Greece, 56403; +302313323188; epist@papageorgiou-hospital.gr), ref: 1274/18/10/2018

Study design
Multicenter interventional double-blind randomised controlled study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Robot-assisted intervention for children with autism spectrum disorder

Interventions
A web-based service was adopted to randomize children into two groups; a social robot-assisted therapy group (NAO group) and a therapist only psychosocial intervention group (control group). Treatment allocations remained concealed from the main researchers until recruitment was irrevocable. The intervention took place in two specialized centers: the pediatric clinic at Papageorgiou General Hospital in Thessaloniki, Greece and the Learning Disabilities center “Praxis” in Kavala, Greece.

The study was conducted over a three month period, with the pretest and the posttest sessions conducted during the first and the last weeks of the study. Two sessions were conducted weekly. Each expert training session involved a triadic context consisting of the therapist, the social robot NAO and the child at the NAO group and a dyadic context consisting of the therapist and the child at the Control group. NAO was programmed and employed as an assistant therapist in the NAO group during 21 intervention sessions. These sessions aimed at instructing the children about social skills e.g. empathy, behavior; control skills e.g. self-regulation and cognitive skills e.g. joint attention, memory and imitation.

Intervention Type
Behavioural

Primary outcome(s)
At baseline, at the end of the interventions and once again after a 3 month period.
1. Autism diagnosis: Childhood Autism Rating Scale (CARS-2;), and Autism Diagnostic Interview–Revised (ADI-R;) were used to confirm autism diagnosis, distinguish autism from other developmental disorders, and plan treatment by personalizing the intervention's sessions.
2. Neuropsychological testing: Wechsler Preschool and Primary Scale of Intelligence (WIPPSI;), and Wechsler Intelligence Scale for Children (WISC-5;) were used to exclude children with cognitive deficits and provide information relevant to cognitive functioning.
3. The Developmental Neuropsychological Assessment (NEPSY–II; Korkman et al., 2007) was used to explore neurocognitive performance.
4. The NEPSY-II subtests of Affect Recognition and Theory of Mind, which form part of the Social Perception domain, were administered to assess the ability to identify emotions, and the ability to understand other's beliefs, intentions, thoughts, and feelings.
5. Parent/Teacher reporting: The Acchenbach System of Empirically Based Assessment (ASEBA; Achenbach & Rescorla, 2001), and the Strengths and Difficulties Questionnaire (SDQ; Cas-Goodman, 1997) were filled out by parents and teachers to assess symptoms, academic difficulties, peer relationship problems, and prosocial behavior problems.

Key secondary outcome(s))
At the end of the interventions:
1. A semi-structured parent interview e.g. questions "name three positive characteristics of your child"; "what is his/her biggest difficulty in everyday life?" was developed by the authors to further adapt the intervention to each child's individual needs.
2. A 9-item satisfaction scale (e.g. items "I am satisfied with the quality of the intervention; I would recommend the intervention to other parents") , rated on a 10 point Likert scale form "not at all agree" to "totally agree", was developed by the authors to explore satisfaction.
3. Children's satisfaction was measured by a questionnaire with 7 closed questions (e.g. items "I feel better since I've been coming here") rated on a 5 point faces scale (with the first face representing "zero satisfaction" and the fifth face representing "total satisfaction") and 3 open questions in the form of sentence completion (i.e "I liked most…"; «I disliked most…"; "My favourite game with the robot was…").

Completion date
27/06/2022

Eligibility

Key inclusion criteria
1. Ages 6 –12 years
2. Confirmed ASD diagnosis
3. IQ over 70
4. Greek-language comprehension
5. CARS-2 from 30 to 37
6. ADI-R: social interaction 10, communication 8 (when verbal ability present) or 7 (verbal ability absent), stereotypic behaviour 3
7. Parents/caregivers written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
12 years

Sex
All

Total final enrolment
51

Key exclusion criteria
1. Co-morbidity with another neurodevelopmental syndrome, photosensitive epilepsy, co-existing disability, organ failure, or other psychiatric disorder that affects functionality or prevents the child from moving freely.
2. Medication that reduces or affects functioning, causes drowsiness, physical symptoms, cognitive impairment, or affects in any way the areas of investigation of the study.

Date of first enrolment
10/01/2020

Date of final enrolment
01/03/2021

Locations

Countries of recruitment
Greece

Study participating centre
Papageorgiou General Hospital
Periferiaki Odos
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Thessaloniki
Greece
56406

Study participating centre
Praxis, Novel therapy and consulting center
El. Venizelou 42
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Greece
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Sponsor information

Organisation
Papageorgiou General Hospital

ROR
https://ror.org/01663qy58

Funder(s)

Funder type
Government

Funder Name
Action “RESEARCH – DEVELOP - INNOVATE”, cycle A, Intervention II, Operational Programme “Competitiveness, Entrepreneurship and Innovation”, NSRF (National Strategic Reference Framework) of Greece 2014-2020 Project no. T1EDK-00929

Results and Publications

Individual participant data (IPD) sharing plan
Data management will be coordinated from the Papageorgiou General Hospital. Access to patient-identifiable data, will be restricted to authorised personnel

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?
Results article		04/11/2022	28/12/2022	Yes	No
Protocol article		01/11/2019	14/02/2022	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes