



**HAL**  
open science

# Pilot study protocol evaluating the impact of telerobotics interactions with autistic children during a Denver intervention on communication skills using single-case experimental design

Carole Fournier, Cécile Michelon, Véronique Granit, Paul Audoyer, Arielle Bernardot, Marie-Christine C Picot, Abderrahmane Kheddar, Amaria Baghdadli

## ► To cite this version:

Carole Fournier, Cécile Michelon, Véronique Granit, Paul Audoyer, Arielle Bernardot, et al.. Pilot study protocol evaluating the impact of telerobotics interactions with autistic children during a Denver intervention on communication skills using single-case experimental design. *BMJ Open*, 2024, 14 (11), pp.e084110. 10.1136/bmjopen-2024-084110 . hal-04826141

**HAL Id: hal-04826141**

**<https://hal.science/hal-04826141v1>**

Submitted on 9 Dec 2024


**HAL** is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.



Distributed under a Creative Commons Attribution - NonCommercial 4.0 International License

# BMJ Open Pilot study protocol evaluating the impact of telerobotics interactions with autistic children during a Denver intervention on communication skills using single-case experimental design

Carole Fournier,<sup>1</sup> Cécile Michelin,<sup>2</sup> Véronique Granit,<sup>2</sup> Paul Audoyer,<sup>2</sup> Arielle Bernardot,<sup>2</sup> Marie-Christine Picot,<sup>3,4</sup> Abderrahmane Kheddar,<sup>1,5</sup> Amaria Baghdadli <sup>2,4,6</sup>

**To cite:** Fournier C, Michelin C, Granit V, *et al*. Pilot study protocol evaluating the impact of telerobotics interactions with autistic children during a Denver intervention on communication skills using single-case experimental design. *BMJ Open* 2024;**14**:e084110. doi:10.1136/bmjopen-2024-084110

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<https://doi.org/10.1136/bmjopen-2024-084110>).

Received 09 January 2024  
Accepted 11 October 2024



© Author(s) (or their employer(s)) 2024. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

## Correspondence to

Professor Amaria Baghdadli;  
rech-clinique-autisme@chu-montpellier.fr

## ABSTRACT

**Introduction** For several years, studies have been conducted on the contribution of social robots as an intervention tool for children with autism spectrum disorder (ASD). One of the early intervention models recommended by the French National Authority for Health is the Early Start Denver Model, an individualised, intensive programme based on play activities chosen by the child. While studies published in recent years suggest that robots provide benefits for autistic children in learning social interactions within a clinical setting, there is no scientific consensus on the widespread contribution and maintenance of their effects over time. On the other hand, a robotic solution controlled directly by a practitioner (ie, on-site telepresence system) enables greater adaptability to children's responses and choices during interventions. We believe that such a solution would enable better assessment of progress in the fundamental skills of expressive communication and imitation as well as greater engagement during interventions.

**Methods and analysis** This is a prospective, monocentric, descriptive and evaluative pilot study based on single-case experimental design (SCED) methodology. The study will recruit eight children diagnosed with ASD aged between 2 and 5 years. The intervention will take place 15 min after the usual weekly care. The SCED methodology is constructed in three stages: (A) 4 weekly sessions at baseline without the robot, (B) 9 weekly sessions with intervention modification using a social robot as cotherapist and (C) 4 weekly sessions without the robot for follow-up.

**Ethics and dissemination** Ethical approval was obtained from the South East IV Ethics Committee (CPP Sud-Est IV) (number: 2023-A00895-40) in France. Explicit consent is required from all legal representatives (parents) of children participating in this study. We aim to disseminate the results of this study through national and international conferences, international peer-reviewed journals and social media.

**Trial registration number** NCT05991791.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study is one of the first to use a teleoperated/telepresence robot as a therapeutic assistance tool to offer the Early Start Denver Model programme to autistic children in a care setting.
- ⇒ On-site teleoperation by therapists is a means of adapting the social robot to the heterogeneity of functioning in autism spectrum disorder.
- ⇒ This study provides a basis for rigorous analysis of the effect and relevance of a robot proposed as a therapeutic tool for use by therapists in a hospital setting.
- ⇒ The robot used in this study has limited dexterity which limits the usual interactions and activities that a therapist could perform.
- ⇒ The use of single-case experimental design methodology is suitable for studying a small group of participants with a heterogeneous clinical profile and without a control group.

## INTRODUCTION

According to recent studies,<sup>1</sup> around 1 in 100 people has an autism spectrum disorder (ASD). Children with this diagnosis show early and lasting disturbances in social communication, particularly with understanding facial emotions. While the positive impact of early non-pharmacological interventions for social communication in ASD is well documented,<sup>2-6</sup> the literature is more limited when it comes to the impact of using robots.

Studies concerning the use of social robots in autistic children<sup>7-9</sup> indicate that they can promote the learning of basic social communication skills. One study also suggests that the effect of this learning is sustainable over time.<sup>10</sup> Nevertheless, the number of studies demonstrating these effects remains small<sup>11 12</sup>



and does not take into account the heterogeneity of ASD by relying on adaptable, autonomous and customisable solutions.<sup>13</sup>

The recommendations of the French National Authority for Health emphasise the value of early, personalised Naturalistic Developmental Behavioural Interventions (NDBIs)<sup>14</sup> in ASD. One such model is the Early Start Denver Model (ESDM),<sup>15</sup> usually administered for at least 20 hours per week per child in some Western countries such as the USA. In France, however, the amount of time spent on this mode of intervention is often less than 5 hours per week due to the lack of sufficient numbers of trained professionals which limits children's progress. Furthermore, one of the aims of the ESDM is to increase positive engagement between a child and a therapist, based on the pleasure of play. However, it can be difficult for a therapist to accurately collect and analyse all of the child's socially adapted or expected behaviours while being fully engaged in the interaction required by the NDBI intervention.

To address this problem, we have developed a research project using a social robot as a therapist's assistant using the DENVER method. This pilot project comprises two phases. The first part (underway since January 2023) aims to train therapists in the use of the social robot Pepper as a tool for observation and therapeutic mediation in routine outpatient care in a child and adolescent psychiatric day care. During the first phase, this remote-controlled robotic system is programmed for easy use by practitioners during interventions on autistic children. The objective of this initial phase is to evaluate the interests and limitations of using robotics in a population of experienced therapists.<sup>16</sup> The second phase of the project (due to start in October 2023 and detailed in this article) includes a clinical trial (the I-ROBI study) which intends to assess the effectiveness of a humanoid robotic tool used routinely in a group of autistic children of varying severity.

The hypothesis proposed by the I-ROBI study is that a teleoperated interactive robot is a relevant therapeutic tool for developing social motivation through play in autistic children.

### Study objectives

The primary objective is to evaluate the effectiveness of a humanoid robotic tool in autistic children as a mediator of learning within the context of ESDM interventions, basic expressive communication and imitation skills using the statistical methodology of single-case experimental design (SCED).

The secondary aims of this study are as follows:

1. To examine whether the levels of engagement and attention of autistic children increase during ESDM intervention on three tasks in the presence of a robot and a therapist compared with two therapists alone.
2. To evaluate the evolution of the child's social communication and imitation skills during the learning process with the robot as measured at each session with an

**Table 1** Example of an ESDM grid for task 1.

Session		
Begin	End	Learning step
		Looks at Pepper/therapist with total physical guidance and performs gestures with total physical guidance.
		Looks at Pepper/therapist with partial physical guidance and performs gestures with partial physical guidance.
		Looks at Pepper/therapist autonomously and performs gestures with partial physical guidance.
		Looks at Pepper/therapist and performs the gestures independently.
		Look at Pepper/therapist and performs the movements independently for at least three consecutive sessions.
		Looks at Pepper/therapist and makes the gestures independently and systematically with three different people and in three different contexts.
<p>'When Pepper/therapist says Hello and Goodbye to the child, the child responds with a look and gestures'. There are six learning steps. At the beginning and at the end of the intervention, the patient is evaluated on this task. A cross or a '+' is put on the grid to indicate that the learning stage has been completed at the end or at the beginning. ESDM, Early Start Denver Model.</p>		

adapted ESDM grid (see [table 1](#)). Communication and imitation skills are evaluated by three tasks (1) task 1 (social skills, level 1, item 8) consists of replying to a greeting request (saying 'Hello' and 'Goodbye'), (2) task 2 (imitation, level 1, item 2) corresponds to the imitation of actions and (3) task 3 (receptive communication, level 1, item 13) is the response to an instruction (giving an object after hearing the instruction 'give') (see [table 1](#)).

3. To evaluate the therapists' satisfaction with the robot's assistance in the care.
4. To evaluate parental satisfaction with the care incorporating the robot.

## METHODS AND ANALYSIS

### Study design

This is a prospective, single-centre, descriptive and evaluative pilot study using the SCED methodology which is based on repeated measurements, with each child acting as his or her own control, and allows greater power with a small sample size.

### Study population

Eight children are included in the protocol and at least three therapists to work with them. Each session involves one child and two therapists: the first therapist leads the session, either face to face with the child during phases A

and C or via the teleoperated robot during phase B; the second therapist is always present with the child, regardless of the phase and offers physical guidance.

Inclusion criteria were being aged 2–5, living in Hérault region, speaking French with at least one of his parents and his/her usual caregivers, having a diagnosis of ASD confirmed by a multidisciplinary clinical assessment. The multidisciplinary clinical assessment includes an Autism Diagnostic Observation Schedule-2 (ADOS-2) evaluation, the Vineland Adaptive Behavior Scale-II (VABS-II), a psychometric test and a speech therapy assessment with Bayley-4 and PLS-5 tests. The language level is collected in the data collection through the module carried out at the time of ADOS-2 but is not an exclusion criterion since none of the tasks requires verbalisation during this research. Children need to receive routine care according to the ESDM model in the Child and Adolescent Psychiatry Department.

The criteria for non-inclusion of children were the absence of written informed consent from at least one legal representative and participation in another research project. Therapists were required to have no history of epilepsy.

Exclusion criteria were parental refusal to participate in the study, withdrawal of consent and loss to follow-up.

### Sample size

On the basis of other studies using the SCED methodology, we consider that a group containing eight children of different ages and levels of severity is statistically sufficient with one measurement taken each week. A study using the SCED methodology must demonstrate its efficacy by reproducing the effects on at least three patients in a single publication<sup>17 18</sup> (see the ‘Data statistical analyses’ section).

### Patient selection, recruitment and initial assessment

Children eligible for the study are those undergoing routine care each week at the Child and Adolescent Psychiatry Department in the University of Montpellier Hospital and referred by their child psychiatrist or psychologist to follow a care programme provided by an experienced multidisciplinary team. Sessions will take place every week from October 2023 to March 2024 for the first group containing four children and from March 2024 to the end of July 2024 with the four other children lasting 15 min (excluding school vacations) after their usual treatment.

All participants selected to join the study in September 2023 for the first session and in January 2024 for the second are invited to a preinclusion visit. During this visit, information is given to participants and/or parents by a child psychiatrist specialist in ASD and a therapist in charge of their care at the Child Psychiatry Department. During this interview, initial information is given about the I-ROBI study, with an explanation of the protocol and handing over of the information note and informed consent form to be signed. Parents are given sufficient

time to reflect on their decision (2–4 weeks). If parents agree to the study, the investigator collects the dated and signed consent form during the first intervention period (see the ‘Ethics and dissemination’ section) as part of routine care which is followed by the research session (I-ROBI) lasting 10–15 min with two research therapists in the Child and Adolescent Psychiatry Department at University of Montpellier Hospital.

Participants are able to stop their involvement at any time and withdraw their consent without justification or detriment to their ongoing care.

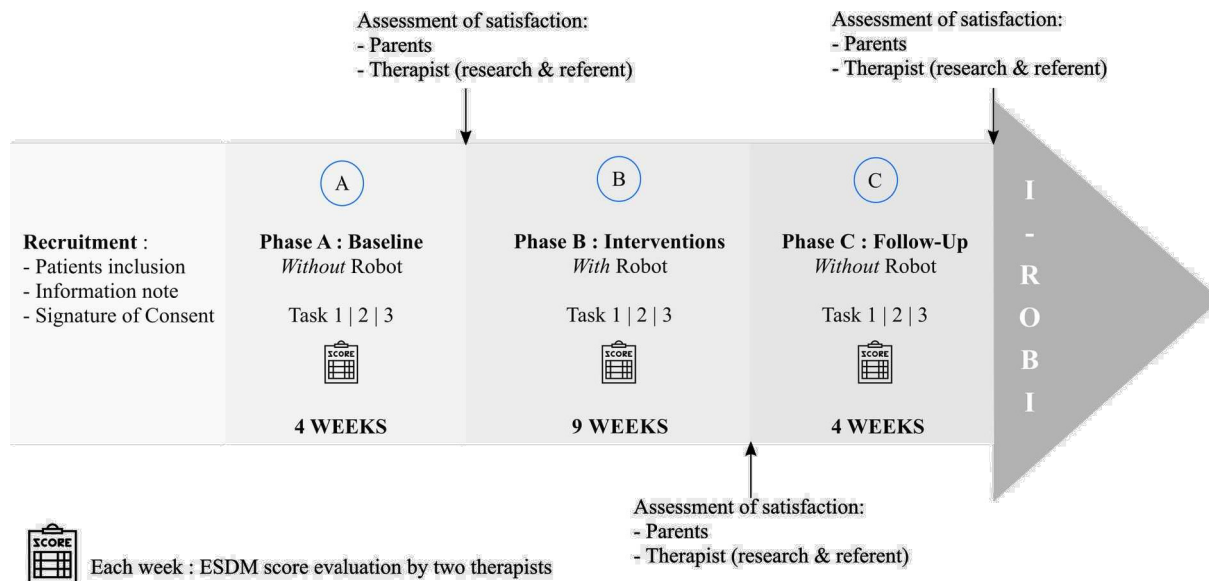
### Description of the intervention

The ESDM<sup>4 19</sup> is a programme developed specifically for intervention in autistic children aged between 12 and 48 months (although it can be used up to a maximum age of 60 months). It aims to improve the social and communicative skills of autistic children. The main advantage of this NDBI intervention is that it is play based.

For such interventions, a skills checklist is set up, enabling the child’s skills to be assessed and learning objectives to be drawn up in collaboration with their referring therapist (therapist providing their routine care). Each objective is divided into several progressive learning stages from basic competence (ie, that observed during the initial assessment) to complete mastery of the objective as defined in Rogers and Dawson.<sup>4</sup>

Several studies have demonstrated the effectiveness of the ESDM model for autistic children, for example, Devescovi *et al.*<sup>19</sup> highlighted that children aged between 19 and 43 months, who had received an ESDM intervention had made larger improvement in communication, social skills and maladaptive behaviours. A 2012 study also showed a marked improvement in children aged 18–30 months<sup>3</sup> in various skills, including language, IQ and social skills after 2 years of therapy.

To improve its feasibility, the I-ROBI study uses an adapted and simplified ESDM programme by only carrying out 15 min interventions, by scoring the child’s progress at the end of the intervention rather than during it and by only using one therapist rather than several during the week as is the case in the USA for example. Only three tasks were chosen to ensure viability of the study within the allotted time (see [table 1](#)). After their usual treatment time each week, participants are taken for 10–15 min sessions with two research therapists who assess the child on the three tasks selected for the project using the ESDM scoring grid. During a 15 min intervention, the role of the first therapist while being physically present in front of the child during phases A and C or as the robot is teleoperated from another room in phase B (so the child only sees the robot and not therapist 1 who is controlling the robot remotely) is to lead the ESDM session, proposing different activities, interacting with the child and giving instructions. In contrast, the purpose of the second therapist is to intervene as little as possible and assist the first therapist by providing physical guidance to the child as the robot cannot. To ensure the feasibility



**Figure 1** The I-ROBI calendar of interventions and collections of data.

of each session's intervention and account for potential professional or personal absences, a minimum of three therapists will be recruited. The therapists' roles with the children should remain as consistent as possible across all sessions, and their involvement will be documented in a logbook.

## Procedure

### Phase A: sessions 1–4: baseline

During phase A, the children included will have four intervention sessions without the presence of the robot before the intervention phase (phase B). SCED experiments require at least three sessions during baseline phase.<sup>20</sup> This phase will last 4 weeks, with the possibility of adding extra weeks if the child misses sessions (eg, absence from the usual session for personal reasons or illness). Following participants' usual weekly individual or group session with their referring therapist, two research therapists will conduct the ESDM session for 10–15 min. Therapists 1 and 2 will conduct the intervention, assess the child on the three tasks selected for the project using the ESDM scoring grid adapted for the study (see [table 1](#)) in a different room to establish a baseline without robot intervention. The level of success will be assessed at the end of each of the four baseline sessions by research therapists 1 and 2 (see [figure 1](#)).

At the end of the four baseline sessions, a satisfaction questionnaire will be completed by the parents, the referring therapist and the research therapist who saw the child most often during the four intervention sessions.

### Phase B: sessions 5–13: intervention

Intervention phase B will begin from session 5 with training on three tasks from the ESDM curriculum, using the Pepper robot remotely operated by research therapist 1. This phase will last 9 weeks with the addition of 2 weeks if sessions are postponed.

The children will have their individual sessions as before, followed by an additional 10–15 min with research therapists who will perform and assess the child on the selected activities with the active help of the robot as a means of interacting with the child. The research therapist 1 who controls the robot will be out of sight of the child in another room during the 15 min intervention. Research therapist 2 will be present in the room with the child, providing physical guidance to interact and guide the child's learning. The robot will be used as a cotherapist whose mission is to facilitate learning of selected tasks, interaction and cooperation between child and therapist.

The first session (session 5) will be 'blank', meaning that the child will have time to familiarise with the Pepper robot which will be present in the room, but without movement and speech, to optimise the child's acceptance of it.

All sessions will be recorded from two points of view: first, with a stationary camera filming the whole room and second, with a camera positioned on the robot's head. Thanks to these video and audio recordings, autonomous ESDM scoring will be set up using on-board algorithms. Prepared tasks are programmed to ensure that the robot keeps count of the number of occurrences of each behaviour, in parallel to the phase B sessions. In addition, the recorded sessions will be used to determine whether or not the solution is of interest to the child by calculating an engagement score with a gaze time to the robot.

At the end of these nine interventions, a satisfaction questionnaire will be completed by the parents, the referring therapist and the research therapist who saw the child most often during the nine intervention sessions. Moreover, research therapist 1 will complete a robot usage questionnaire at the end of each intervention session.

### Phase C: sessions 14–17: postintervention

Finally, during sessions 14–17 (postintervention, follow-up, phase C), the two therapists will continue to treat the child over 10–15 min in addition to their usual therapy for the purpose of assessing the persistence of the gains made during the phase B sessions without the help of the robot.

At the end of the four follow-up sessions, a satisfaction questionnaire will be completed by the parents, the referring therapist and the research therapist who saw the child most often during the four intervention sessions.

### Common to all phases

Each session intervention will conclude with the completion of an adapted ESDM grid by both research therapists. The grids are the same as the ones the robot completed for the three tasks included in the study goals. The grid's findings will be translated into scores. Task 1 has six learning steps, hence the maximum score is 6. Tasks 2 and 3 have maximum scores of 7. The maximum score, 7 points, indicates how many steps it takes to determine if a skill has been learnt. For example, if at the beginning and at the end the child 'Looks at Pepper/the therapist with partial physical guidance and performs gestures with partial physical guidance', the child will score 2 points for this session. If the child performs only at the beginning of this level, the score will be 1.5.

### Global data collection

The pseudonymised data from the study will be entered into a database created using Excel software and designed in accordance with the quality procedures used at University of Montpellier Hospital. The database will be only accessible to authorised persons and must contain all the information required by the protocol. The method of data collection is approved by the French Data Protection Authority (CNIL: Commission nationale de l'informatique et des libertés) (Reference: TD/MJT/AR2315530).

### Collected data

#### Clinical and sociodemographic data

This type of data will be collected using the participant file and/or during the parental interview before the start of the intervention programme. The data targets included age and sex of the child, parental socioprofessional status and education level, the number of siblings and rank, child's adaptive levels (VABS II) and intensity of ASD symptoms (ADOS 2 total score), childcare and/or education.

#### Data from the robot

The video data will be pseudonymised (initials surname and first name+inclusion number) and stored in a folder shared within the Clinical Research and Epidemiology Unit in Montpellier Hospital. The video data will be shared with an engineer of the Laboratory of Computer Science, Robotics and Microelectronics of Montpellier (LIRMM) with limited access. Data collected during an intervention will include the video recording by camera

of the sessions in the whole room (camera independent of the robot), video feedback from the camera installed on the robot (only during phase B), global audio feedback from the therapist, the robot and the child.

### Data on the intervention with and without the robot

Two ESDM scoring grids will be completed by the research therapists at the end of each intervention for the three phases (A, B and C). The research therapists are the two therapists present during the intervention: the one controlling the robot and the assistant during phase B and the one leading the intervention with the robot and the assistant during phases A and C. These data will be collected and entered into the database in the form of an Excel document hosted on the hospital servers where all data will be stored.

### Data quality control procedures

Regulatory aspects are monitored during the study by a clinical trial sponsor from University of Montpellier Hospital Centre. Once a year, the sponsor checks the consent and the inclusion curve. A written monitoring report will be drawn up for each visit. The biostatistician and a PhD student will check the database completion rate on a monthly basis in order to increase data completeness.

### Internal validity verifications

To ensure the validity of the study, two criteria will be taken into account: (1) the inter-rater reliability (IRR) and (2) the procedural fidelity. Each of these criteria will be evaluated for a minimum of 20% of the sessions administered by each research therapist at each phase<sup>17</sup> (20% of the phases A, B and C). Based on the 17 sessions per child, 32 sessions will be evaluated.

The IRR will be measured for each of the three tasks. The reference score will be the one of the main therapist (th1) which will be compared with the one of the second therapist (th2). An external person on the project will also quote the sessions with video and be compared with the main therapist scores.

To evaluate the reliability between each scorer, we will also plot the data on three graphics and evaluate if the curves are following the same trends. If so, it means that the scorer has an influence on the severity of the score but that the progress is identified in the same way. Thus, it means we can trust the scorer's results.

The procedural fidelity will be evaluated thanks to the external recording video of each session. To ensure procedural fidelity, the following information will be checked:

- ▶ The intervention sessions last more than 10 min and less than 16 min.
- ▶ th1 must say 'Hello' at the beginning of the sessions and 'Goodbye' at the end of each intervention and wait for an answer from the child (th2 add guidance if necessary).
- ▶ th1 must ask to the child, at least five times in one session, to give an object.



- ▶ th1 must propose at least five different gestural imitations during the session.
- ▶ th1 and th2 complete the grid immediately and independently after the sessions, without any prior consultation.
- ▶ The session is led by the same research therapists as in the previous session.
- ▶ Only two therapists must be present during the intervention.
- ▶ At least five different toys must be present in the room so the child can choose its own activity.

Additionally, based on a template, a logbook will be created for each session that will include the following information: the suggested and completed activities, the primary and guiding therapists, the start and end times of the session, the child's overall mood for the day, the ESDM rating grids for each therapist and any additional remarks from the therapists. We will be able to track any deviations that might happen throughout our activities thanks to this logbook.

### Data collection and management

In order to preserve anonymity, participants are identified in the observation booklet by a unique identification number. A participant identification list is kept in the investigator's file. The investigator ensures that the anonymity of each person taking part in the research is guaranteed. Information is collected for each participant in a standardised observation book filled in by the investigator, the coinvestigator or the clinical trial technician in charge of the study.

### Data statistical analysis

The statistical analysis will be conducted in two studies: (1) the first phase to evaluate the effect of the intervention during the clinical phase and (2) a second evaluation will be conducted in a separate study based on these results, to assess the accuracy and relevance of an algorithm designed for the automatic assessment of ESDM score using the ESDM grid.

In this initial statistical analysis, we will assess the effects of the interventions by performing both a visual and statistical analysis for each task (task 1, task 2, task 3 and the number of gazes) for each individual child. After this individual analysis, we will compare the results across the different children for each task to assess whether a positive effect is associated with the introduction of the robot.

First, to assess the effects of the intervention on the selected task, statistical analysis will be carried out using the SCED method based on the collection of repeated and frequent measurements throughout the study protocol. For each child in ABC design, two replications of the effect are possible, comparing phases A–B and B–C. The phase C has three roles: (1) observe if there is a change of level between intervention and new baseline, and if the level is the same as during the first phase A. If it is, it suggests that intervention has had an effect<sup>21</sup>; (2) if it returns to the first baseline values it also confirms

what would be the baseline behaviour if not taking care of and (3) it can be considered as a follow-up phase to see if the skills learns or not in the intervention (if applicable) are maintaining through time after the intervention. By comparing the trend, median and variability measured and observed with the usual method (therapists alone) to the measurements taken in the therapeutic phase (phase B), and in the follow-up phase (phase C), the impact of the intervention can be precisely determined. If we found three repetitions of effect between the two same phases ((A vs B) or (B vs C)) across the eight participants, we will be able to conclude the relative positive or negative effect of the intervention according to SCED standards.<sup>17</sup>

This visual analysis will be completed by the Visual Aid Implying an Objective Rule Protocol<sup>22</sup> which also studies the trends variability and level of data but includes a direct comparison between two distinct phases. If a point is below the trend line of the precedent phase, the point is represented in red, if the point is over the trend is it green and if it is between the 2 SD around baseline it is yellow as the example displayed in figure 2.

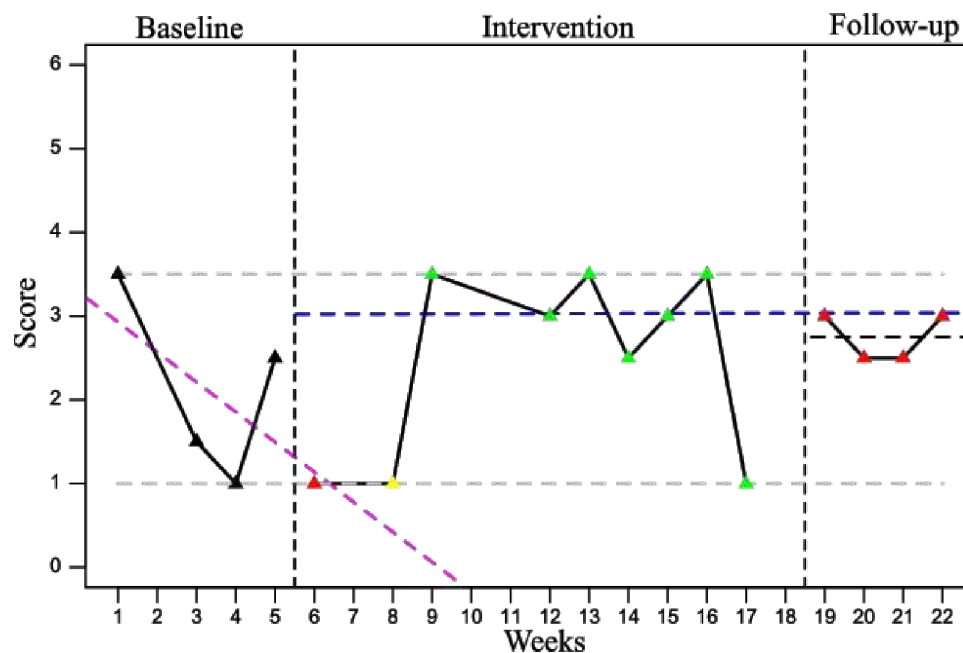
The visual analysis will be complemented with the statistical analysis which will take into account the overlap rate. The overlap rate will be obtained by calculating the number of overlapping points between phases: the more overlap there is between two phases, the less interventional effect there is. Conversely, if two phases show no measurement overlap then intervention is likely to have a greater impact. Numerous overlap techniques exist. Those that will be used for this study will be (1) the 'non-overlap of all pairs—NAP' technique,<sup>23</sup> (2) the tau-U coefficient and (3) baseline-corrected tau-U.<sup>24</sup>

The non-parametric statistical coefficient tau-U and baseline corrected tau which remove the baseline trend if there is a significant monotonic baseline trend<sup>23</sup> will be used to evaluate the effect of the intervention between phases. This value will complete the NAP value and represent the strength and direction of the effect size of the treatment over phases.<sup>25</sup>

### Methodological considerations

The risks associated with participation in this protocol are low and one adverse event could be the child's refusal to carry out the task in the presence of the robot due to fear. In the event of unwillingness, the child will continue his or her usual intervention with his or her referring therapist without the presence of the robot.

Although some studies have highlighted that the loss of previously acquired skills is a characteristic of autism, particularly in the areas of language and general social engagement,<sup>26 27</sup> it is possible that certain behaviours may not be reversible over time, and that no changes are observed between phases B and C. In this case, it will be more difficult to demonstrate an immediate positive effect of the robot's introduction, because with only three phases, we will only show the effect of the robot on the level of results at a specific point in time (between phases A and B).



**Figure 2** Example of visual representation of the score for a Task according to weeks (each session is represented by a triangle mark), during phase (A) Baseline (B) Intervention (C) Follow-up. The pink line represents the trend of phase A; the blue line of phase B and dark line of phase C. The grey lines represent the minimum and maximum values of phase A.

In the absence of changes in skill levels, we will focus on comparing the learning trend. If no changes are observed, it would mean that the robot has no effect. But if a change in trend is observed, it would mean that the robot has a positive or negative effect on the targeted behaviour, and that this effect may or may not be sustained over time.

## ETHICS AND DISSEMINATION

### Research ethics approval

This research project has been approved by the South-East IV Ethics Committee for Research Conducted on Human Beings (CPP Sud-Est IV) in France (number: 2023-A00895-40). The research is conducted in compliance with current French regulations, specifically the provisions relating to research involving human beings.

### Information to participants and consent

Prior to carrying out this research involving human beings, the free informed consent (category 2) from at least one of the legal representatives for the participating minor must be obtained after they have been informed by a doctor and following a sufficient period of reflection (1–2 weeks).

### Patient and public involvement

Research and clinical therapists were involved in the design, the conduct and the dissemination plans of this research. Parents and patients were not involved.

### Dissemination policy

The results will be presented at various national/international congresses and conferences and may be published in high-impact scientific journals such as *Science Robotics*

(IF=23.748); *The Lancet Child & Adolescent Health* (IF=37.746); *IEEE Robotics and Automation Letters* (IF=4.321); *International Journal of Social Robotics* (IF=3.802).

## DISCUSSION

This study is being carried out in response to the lack of adaptable robotic solutions for therapeutic intervention in autistic children. It will enable us to evaluate the impact of an adaptable robotic solution using teleoperation on the effects of learning basic communication during ESDM interventions. We also hope to be able to measure the effects over time of this type of intervention with the 4-week follow-up phase. Indeed, the relevance of this strategy also depends on the reproducibility of learning with individuals and the durability of effects after the end of the robotic interventions.

This study will also provide us with other time-saving feedback for professionals due to the automatic assessment of the child's skills and the production of a standardised intervention report. We hope that this empowerment will reduce the workload of therapists during sessions so that they can focus on the quality of interactions rather than on memorising clinical data such as gaze time, reaction time, number of repetitions, etc.

If we can confirm an impact on the child's ability to learn communication skills and a reduction in the mental workload of therapists due to the empowering findings contained in the reports, our next step will then be to authorise the robot to perform additional tasks based on the ESDM model. Since it is not feasible for professionals to offer 20 hours of ESDM per week to a child in France,



a robotic assistant would be a crucial help to achieve this number of hours and could provide a solution for administering daily care at home.

Depending on the results of our work, it will be interesting to make comparisons with other studies where robots have provided assistance in other models of care for autistic children (eg, Applied Behavior Analysis (ABA) or psychomotor therapy).

### Expected outcomes

The expected outcomes are (1) the use of the robot as a cotherapist in therapy could bring additional benefits compared with conventional therapy without a robot; (2) an improvement in the care pathway by increasing the number of hours of specific interventions as recommended by the French National Authority for Health (HAS) which thereby fosters development of social skills in the children benefiting from it and (3) earlier attainment of therapeutic objectives, enabling shorter patient intake times.

### Author affiliations

<sup>1</sup>UMR5506 CNRS - Laboratory of Computer Science, Robotics and Microelectronics of Montpellier (LIRMM), Montpellier, France

<sup>2</sup>Languedoc-Roussillon Autism Resource Centre and Centre of Excellence for Autism and Neurodevelopmental Disorders (CeAND), University of Montpellier Hospital Centre, Montpellier, France

<sup>3</sup>Clinical Research and Epidemiology Unit (Public Health Service), University of Montpellier Hospital Centre, University of Montpellier, Montpellier, France

<sup>4</sup>University of Paris-Saclay, UVSQ, Inserm, CESP, Team DevPsy, Villejuif, France

<sup>5</sup>IRL3218 CNRS-AIST Joint Robotics Laboratory, Tsukuba, Japan

<sup>6</sup>Faculty of Medicine, University of Montpellier, Montpellier, France

**Acknowledgements** The Authors would like to thank all the families and children who agreed to take part in the 19 weeks of intervention for this study as well as the therapists in charge of each of the children in the Early Childhood Department at the Day Hospital who agreed to help ensure that the study ran as smoothly as possible and liaise with the families.

**Contributors** CF, AB, AK and CM conceived the study and wrote the manuscript. PA, VG and AB participated in the design of an ESDM intervention model in this research protocol compatible with the robot's capabilities and the usual management method. M-CP was involved in setting up and validating a coherent methodology. CF, AB and AK were involved in developing the research questions and the state of the art of this topic. AB and AK critically reviewed this article and commented on it before approving the final version. The guarantor of the study is AB; accepts full responsibility for the finished work and/or the conduct of the study, has access to the data and controls the decision to publish.

**Funding** This work is supported by the University of Montpellier Hospital Centre through a Tremplin project (Promoter ID: RECHMPL23\_0056), grant (No ID-RCB : 2023-A00895-40). The project is also funded by a doctoral grant from the Occitanie Region. The technological and robotic equipment is on loan from AK.

**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Consent obtained from parent(s)/guardian(s).

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Open access** This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

### ORCID iD

Amaria Baghdadli <http://orcid.org/0000-0002-5679-7544>

### REFERENCES

- 1 Zeidan J, Fombonne E, Scora J, *et al*. Global prevalence of autism: A systematic review update. *Autism Res* 2022;15:778–90.
- 2 Foxx RM. Applied behavior analysis treatment of autism: the state of the art. *Child Adolesc Psychiatr Clin N Am* 2008;17:821–34.
- 3 Dawson G, Jones E, Merkle K, *et al*. Early behavioral intervention is associated with normalized brain activity in young children with autism. *J Am Acad Child Adolesc Psychiatry* 2012;51:1150–9.
- 4 Rogers SJ, Dawson G. *Early Start Denver Model for Young Children with Autism: Promoting Language, Learning, and Engagement*. 2009.
- 5 Geoffroy M-M, Denis A, Mengarelli F, *et al*. USING ESDM 12 HOURS PER WEEK IN CHILDREN WITH AUTISM SPECTRUM DISORDER: FEASIBILITY AND RESULTS OF AN OBSERVATIONAL STUDY. *Psychiat Danub* 2019;3:333–9.
- 6 Christensen DL, Bilder DA, Zahorodny W, *et al*. Prevalence and Characteristics of Autism Spectrum Disorder Among 4-Year-Old Children in the Autism and Developmental Disabilities Monitoring Network. *J Dev Behav Pediatr* 2016;37:1–8.
- 7 Cabibihan J-J, Javed H, Ang M Jr, *et al*. Why Robots? A Survey on the Roles and Benefits of Social Robots in the Therapy of Children with Autism. *Int J Soc Robotics* 2013;5:593–618.
- 8 Mayadunne M, Manawadu UA, Abeyratne KR, *et al*. A robotic companion for children diagnosed with autism spectrum disorder. International Conference on Image Processing and Robotics; 2020:1–6.
- 9 Ivani AS, Giubergia A, Santos L, *et al*. A gesture recognition algorithm in a robot therapy for ASD children. *Biomed Signal Process Control* 2022;74:103512.
- 10 Scassellati B, Boccanfuso L, Huang CM, *et al*. Improving social skills in children with ASD using a long-term, in-home social robot. *Sci Robot* 2018;3:eaat7544.
- 11 Puglisi A, Capri T, Pignolo L, *et al*. Social Humanoid Robots for Children with Autism Spectrum Disorders: A Review of Modalities, Indications, and Pitfalls. *Children (Basel)* 2022;9:953.
- 12 Kouroupa A, Laws KR, Irvine K, *et al*. The use of social robots with children and young people on the autism spectrum: A systematic review and meta-analysis. *PLoS ONE* 2022;17:e0269800.
- 13 Santos L, Annunziata S, Geminiani A, *et al*. Applications of Robotics for Autism Spectrum Disorder: a Scoping Review. *Rev J Autism Dev Disord* 2023.
- 14 Sandbank M, Bottema-Beutel K, Crowley S, *et al*. Project AIM: Autism intervention meta-analysis for studies of young children. *Psychol Bull* 2020;146:1–29.
- 15 Geoffroy M-M, Denis A, Mengarelli F, *et al*. Using ESDM 12 hours per week in children with autism spectrum disorder: feasibility and results of an observational study. *Psychiat Danub* 2019;31:333–9.
- 16 Fournier C, Michelon C, Tanguy A, *et al*. A pilot usability study of a humanoid avatar to assist therapists of asd children. In: *Social Robotics. ICSR 2023. Lecture Notes in Computer Science*. Singapore: Springer, 2023.
- 17 Krasny-Pacini A, Evans J. Single-case experimental designs to assess intervention effectiveness in rehabilitation: A practical guide. *Ann Phys Rehabil Med* 2018;61:164–79.
- 18 Tate RL, Perdices M, Rosenkoetter U, *et al*. The Single-Case Reporting Guideline In Behavioural Interventions (SCRIBE) 2016: Explanation and elaboration. *Arch Clin Psychol* 2016;4:10–31.
- 19 Devescovi R, Colonna V, Dissegna A, *et al*. Feasibility and Outcomes of the Early Start Denver Model Delivered within the Public Health System of the Friuli Venezia Giulia Italian Region. *Brain Sci* 2021;11:1191.
- 20 Tate RL, Perdices M. *Single-Case Experimental Designs for Clinical Research and Neurorehabilitation Settings: Planning, Conduct, Analysis and Reporting*. 2019.
- 21 Kazdin AE. *Single-Case Research Designs: Methods for Clinical and Applied Settings*. 2nd edn. New-York: Oxford University Press, 2011.
- 22 Manolov R, Vannest KJ. A Visual Aid and Objective Rule Encompassing the Data Features of Visual Analysis. *Behav Modif* 2023;47:1345–76.
- 23 Parker RI, Vannest K. An improved effect size for single-case research: nonoverlap of all pairs. *Behav Ther* 2009;40:357–67.
- 24 Tarlow KR. An Improved Rank Correlation Effect Size Statistic for Single-Case Designs: Baseline Corrected Tau. *Behav Modif* 2017;41:427–67.
- 25 Brossart DF, Laird VC, Armstrong TW. Interpreting Kendall's Tau and Tau- U for single-case experimental designs. *Cog Psych* 2018;5:1518687.

- 26 Barger BD, Campbell JM, McDonough JD. Prevalence and onset of regression within autism spectrum disorders: a meta-analytic review. *J Autism Dev Disord* 2013;43:817–28.
- 27 Havdahl A, Farmer C, Surén P, *et al*. Attainment and loss of early social-communication skills across neurodevelopmental conditions in the Norwegian Mother, Father and Child Cohort Study. *J Child Psychol Psychiatry* 2024;65:610–9.