An exploratory study on the effectiveness of Pivotal Response Treatment and a robot-based Pivotal Response Treatment on social and communicative skills in children with autism spectrum disorder

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Developmental disorders NEC
Study type	Interventional

Summary

ID

NL-OMON41835

Source
ToetsingOnline

Brief title
PicASSo

Condition

- Developmental disorders NEC

Synonym
autism, autism spectrum disorder

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: ZonMW PTO project no. 95103010

Intervention

Keyword: Autism spectrum disorder, Pivotal Response Treatment, Robots, Social skills

Outcome measures

Primary outcome

1) Clinically significant response (reduction of more than 25%) on the Social Responsiveness Scale (SRS): improvement in social and communicative skills in the child*s natural environment (generalization of skills), rated by a parent and teacher of the child.

2) Clinically significant response on the CGI: improvement in mental health (score much improved or very much improved), rated by a child psychiatrist, blind to the intervention conditions.

3) Significant decrease on the ADOS severity score: decrease in ASD symptoms

Secondary outcome

1) Improvement in communicative skills during PRT interventions: specific communicative skills that are targeted by the PRT with the level of help (prompts) that is needed by the child to perform these skills are assessed in the Robot-based PRT condition and PRT condition. A 15-minute PRT screening scenario is developed and simulated at 4 measurement points.

2) Spontaneous appropriate behaviour in learning moments during PRT: in the robot-based PRT sessions and PRT sessions, a percentage is calculated for the amount of learning moments the child shows spontaneous appropriate behaviour in.

3) Child-rearing pressure experienced by parents: this is assessed with a digital questionnaire called the "OBVL", at 4 moments in the study

4) Likability of the robot by the child: after each session that involves the robot within the robot-based PRT condition, the child is asked how much he or she likes the robot using a 5-point VAS line.

5) Child's affect during robot-based PRT sessions: before and after each session involving the robot within the robot-based PRT condition, the child is asked how he or she feels at that moment using a 5-point VAS line.

6) Salivary cortisol, oxytocin and testosterone: Before and after PRT session 1, 10 and 20, the child is asked to gently spit in a plastic tube.

Study description

Background summary

Children with autism spectrum disorder (ASD) are characterized by persistent deficits in social communication and social interaction. Despite the severity and chronic course of the disorder, the heavy burden on individuals and families, the high prevalence rate and the high societal costs, no effective

pharmacologic treatments are available for targeting the core symptoms of ASD. As a behavioural intervention, Pivotal Response Treatment (PRT) has been proven effective in improving different social and communicative skills in children with ASD. Additionally, studies focusing on implementing robotics in the treatment of children with ASD show promising results. Although promising, earlier studies to the effectiveness of PRT and implementing robots in the treatment of children with ASD are limited by methodological problems. The current study will address these problems by conducting a randomized clinical trial to the effectiveness of PRT with and without the implementation of a humanoid robot.

Study objective

The primary objective of the current study is assessing the effectiveness of robot-based PRT on top of care-as-usual compared to care-as-usual only.
The primary hypothesis is:
1) Robot-based PRT is more effective compared to care-as-usual only in:
-promoting social and communicative skills in children with ASD (within the natural environment of the child)
-providing a clinically significant improvement on mental health
-decreasing severity of ASD symptoms

Secondary objectives/hypotheses:
2) PRT provided by a human trainer is more effective compared to care-as-usual in:
-promoting social and communicative skills in children with ASD (within the natural environment of the child)
-providing a clinically significant improvement on mental health
-decreasing severity of ASD symptoms

3) Robot-based PRT and PRT provided by a human trainer are effective in:
-promoting social and communicative skills in children with ASD (within the natural environment of the child)
-providing a clinically significant improvement on mental health
-decreasing severity of ASD symptoms

Besides measuring generalization of social and communicative skills into the natural environment of the child, the interest is in assessing the improvement in skills during the treatment and assessing the likability of the robot by the children with ASD and the affect of the child within the robot-based PRT. This provides more information on the usefulness of implementing a robot in the treatment of children with ASD.
Hypotheses:
4) Robot-based PRT is more effective compared to PRT provided by a human trainer in:
-lowering the prompt level (i.e. help that is needed) for communicative skills in children with ASD during treatment

-heightening the number of learning moments the child shows spontaneous appropriate behaviour (e.g. initiations) on during the treatment
5) The robot that is used in the robot-based PRT shows a high likability by children with ASD
6) Children with ASD show positive affect during the robot-based PRT sessions

Also, child rearing pressure on parents is administered, because of the highly parent-focused PRT.
7) Robot-based PRT and PRT provided by a human trainer are both effective in decreasing the child rearing pressure experienced by parents.

Additionally, interest is in the relation between questionnaire data about social behaviour and qualitative reports on robot experiences on the one hand and possible physical makers of social behaviour and stress on the other.
8) Qualitative affect scores during PRT are related to salivary cortisol levels
9) Social and communicative skills in children with ASD are related to salivary oxytocin and testosterone levels

Study design

The study is designed as an exploratory cluster-randomized (phase IIa - like) open three-group parallel clinical trial. Subjects are cluster-randomly assigned to three intervention conditions:
1) Robot-based PRT: Therapy is provided based on Pivotal Response Treatment with the implementation of a humanoid robot on top of care-as-usual, i.e. psycho-education and medical management (n = 25)
2) PRT: Pivotal Response Treatment is administered by a human trainer on top of care-as-usual, i.e. psycho-education and medical management (n = 25)
3) Care-as-usual: includes guidance of parents or intensive psychiatric family treatment, besides psycho-education of ASD and medical management (n = 25)

The randomization occurs per cluster. For 4 locations of Karakter, randomization occurs between robot-based PRT and care-as-usual and for 3 locations of Karakter, randomization occurs between PRT and care-as-usual.

The study consists of a selection phase, randomization phase, baseline measures, a 5-month intervention phase including evaluation measures and follow-up measures (3 months after the end of the intervention).

Intervention

The study consists of 3 intervention conditions, to which participants are cluster-randomly assigned:

1) Robot-based PRT, on top of care-as-usual (robot therapy condition): includes 20 sessions, once a week of 45 minutes. During the sessions, learning moments

are created that provide the child the opportunity to e.g. learning to initiate within a social conversation. The content of the sessions is focused on different social and communicative skills and depends highly on the learning goals, that are determined on forehand. Within all parent-child sessions (14), a humanoid robot called NAO from Aldebaran robotics is used. The robot can speak and move, facilitating social interaction with the child. A trained PRT therapist is present during all robot-based PRT sessions. In addition to the robot-based PRT, care as usual (psycho-education and medical management if applicable) is provided.

2) PRT by a human trainer, on top of care-as-usual (PRT condition): includes 20 sessions, once a week of 45 minutes. PRT is provided by a human PRT-therapist, as is the regular procedure within Karakter. As in the robot-based PRT, the focus is on improving different social and communicative skills, depending on the learning goals of each child. The main focus is on teaching parents to implement PRT principles in social situations with their child, based on the strengths of parents.

3) Care-as-usual: includes the regular treatment for ASD that is provided in outpatient departments of Karakter. The care-as-usual condition includes psycho-education of ASD and medical management, supplemented by guidance of parents and other primary caregivers or intensive psychiatric family treatment.

Study burden and risks

The risks of participating in the study are estimated to be very low. No adverse effects have been described in earlier studies that implemented a humanoid NAO robot within treatment of children with ASD. Patients assigned to the three conditions are all expected to benefit from their treatment. Additional time investement for participation in this therapeutic study is low compared to regular procedures for treatment of ASD and measuring treatment effects within Karakter. The robot-basedl PRT and PRT are provided in addition to the basic care as usual for ASD within the outpatient department of Karakter. Changes in dosages of medication are not allowed during the study. When changes in the child's behaviour are noticed, this is reported and the responsible child psychiatrist is contacted to assure optimal care for each child. The benefits of participating in the study are expected to highly outweight the possible disadvantages.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

-aged 3-8 years at start of the intervention
-clinically diagnosed with ASD, confirmed by the Autism Diagnostic Observation Schedule.
-a total intelligence quotient of > 70
-ability to speak single words at least
-at least one parent speaks Dutch to the child at home

Exclusion criteria

-medication dosages cannot be fixed during the study
-having received PRT earlier

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2015
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO Date:	08-01-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-04-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL50509.091.14
Other	NTR nr. 4712