Prt-based Interventions with robots for training Childen with AutiSm in SOcial and communicative skills

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29129

Source
NTR

Brief title
PicASSo

Health condition

Autism
Autism Spectrum Disorder
Pivotal Response Treatment
PRT
intervention
robots
social skills
communicative skills

Sponsors and support

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Source(s) of monetary or material Support: ZonMW – The Netherlands Organisation for Health Research and Development
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PTO project no. 95103010

Intervention

Outcome measures

Primary outcome

1) Report of partent and teacher:

-Social Responsiveness Scale (SRS): ASD symptoms of the child, with the focus on social and communicative skills

2) Report of child psychiatrist:

-Clinical Global Impression Improvement Scale (CGI-I): a general impression on the improvement in mental health of the child with ASD

Secondary outcome

Rated by trained psychologist:

1) Prompting requirement of communicative skills (CS) during PRT sessions

2) Number of learning moments (LM) in which the child shows spontaneous appropriate behaviour (e.g. initiations)

Rated by child:

3) Visual Analogue scale (VAS): likability of the robot and child's affect during PRT robot treatment

Study description

Background summary

Autism spectrum disorder (ASD) includes deficits in social communication and social interaction that are presistent across lifespan. Despite the heavy burden on individuals and their families, the high prevalence of ASD and the high costs for society, no effective

pharmacologic interventions are currently available to treat the core symptoms of ASD. Pivotal Response Treatment (PRT), an approach based on principles of applied behaviour analysis (ABA), has been proven effective in promoting social and communicative skills in children with ASD. Also, implementing robots in the treatment of children with ASD seems promising due to the intrinsic attractiveness to these children an the robot behaviour that can be controlled and easily adjusted in complexity.

Although results are promising, earlier studies to the effectiveness of PRT and the implementation of robotics into the treatment of ASD show metholodigcal limitations, such as small sample sizes and the lack of an experimental design. Also, there is a lack of studies that integrate robotics into an empirically supported treatment for children with ASD.

The current study will address the limitations in earlier studies by:

-conducting a well-designed randomized clinical trial

-including a relatively high number of participants (i.e. 75)

-confirming diagnosis of ASD by 'gold standard' instruments

-including both quantitative and qualitative measures of treatment effectiveness

-implementing a robot into an empirically supported treatment for children with ASD (i.e. PRT)

-measuring generalization of skills into the natural enviroment of children

Study objective

Primary hypotheses:

1) Pivotal Response Treatment (PRT) with the implementation of a robot is more effective compared to PRT provided by a human trainer and compared to care-as-usual only in:

-promoting social and communicative skills in children with ASD (reduction ASD symptoms measured by the SRS)

-providing a clinically significant improvement on mental health (measured by the CGI Improvement Scale)

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 (reduction ASD symptoms

measured by the SRS)

-providing a clinically significant improvement on mental health (measured by the CGI Improvement Scale)

Secondary hypotheses:

3) PRT with the implementation of a robot 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/initiations on during the treatment

4) The robot that is used in the PRT robot intervention shows a high likability by children with ASD

5) Children with ASD show positive affect during the PRT robot sessions

Study design

After administration of measures for assessing inclusion criteria (i.e. demographic information, ADI-R, ADOS, Wechsler scales), the outcome measures are adminitered at the following time points:

-week 0: baseline: SRS, CGI-I in all intervention groups, CS in PRT intervention groups

-week 1-20: intervention: LM in PRT intervention groups, VAS in PRT robot intervention group

-week 5,10,15,20: SRS, CGI-I in all intervention groups, CS in PRT intervention groups

-week 32: follow-up: SRS, CGI-I in all intervention groups, CS in PRT intervention groups

Intervention

The study includes 3 intervention conditions, to which participants will be randomly assigned:

1) PRT robot intervention on top of care-as-usual: 20 session of PRT, 30-45 min once a week with the implementation of a robot in the treatment. Pre-progammed scenarios will be used, as well of a text-to-speech functionaliy in which the trainer can instantly fill in the sentences

of the robot and provide reinforcement.

2) PRT intervention on top of care-as-usual: PRT that is provided by a human trainer, 20 sessions of 30-45 min once a week

3) care-as-usual: includes different treatments, mainly psycho-education and guidance of partents. Duration is variable.

Contacts

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Eligibility criteria

Inclusion criteria

-children aged 3-8 years with a diagnosis of ASD, confirmed by the Autism Diagnostic Interview - Revised (ADI-R) and Autism Diagnostic Observation Schedule (ADOS)

-IQ > 70

-is able to speak single words at least

-at least one parent speaks Dutch to the child at home

Exclusion criteria

-children of whom medication dosis cannot be fixed during the study

-children who received PRT earlier

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2015
Enrollment:	75
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	01-08-2014
Application type:	First submission

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
NTR-new	NL4487
NTR-old	NTR4712
Other	CMO Arnhem-Nijmegen : ZonMW PTO project no. 95103010

Study results