Effectiveness of Pivotal Response Treatment: Plasticity of emotion regulation in young children.

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

Summary

ID

NL-OMON39370

Source
ToetsingOnline

Brief title
Plasticity of emotion regulation in young children.

Condition

- Developmental disorders NEC

Synonym
Autism, Autism Spectrum Disorders

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: WOP subsidie GGZ Rivierduinen;Centrum Autisme

Intervention

Keyword: Autism, Emotion regulation, Parent-Child interaction, Pivotal Response Treatment

Outcome measures

Primary outcome

The main study outcome is the change in overall functioning of children with ASD, due to the PRT intervention, as expressed in scores on questionnaires and behavioral observations.

We aim to predict these changes in overall functioning from child and parent characteristics on three different measurement levels. Physiological measures, as expressed in heart rate, skin conductance, and salivary cortisol. Cognitive measures, as expressed in intellectual functioning, social cognition, language and executive functioning. And finally, involving behavioral measures as expressed in questionnaires and behavioral observations.

For a detailed overview on all the study parameters (categorized by measurement level and by child- or parent characteristics), and their abbreviations, see Table 3 of the research protocol.

Secondary outcome

Child*s background information:

The parent will fill in a questionnaire concerning overall psychopathology (CBCL). This questionnaire will be used as a categorical screener for general problem behavior that might cause or mask differences on variables of interest and therefore need to be controlled for.

Parent*s background information:

Parents will fill in a questionnaire concerning their motivation for their present situation to change (PMI). In addition a psychiatric structured interview will be administered with mother (MINI-plus) to screen for possible overall psychopathology.

Study description

Background summary

Children with an Autism Spectrum Disorder (ASD) experience severe problems in social functioning which pose a serious threat on the development of several different domains of general functioning. To reduce the impact of the ASD on the development of these children it is of major importance to be able to influence their social competencies in a positive matter. For example, interventions that aim to enhance the motivation for interaction by early stimulation of positive interactions between parents and children using Pivotal Response Treatment (PRT) proves to provide favorable results. PRT is an established and scientifically supported treatment protocol aimed at increasing the motivation for interaction in children with ASD by stimulating the interaction between parents and children. (Coolican, Smith, and Bryson, 2010; Smith, Koegel, Koegel, Openden, Fossum, and Bryson, 2010). For a more detailed description of PRT and its content, see Appendix I. Previous research on PRT has shown improvements in social interaction and even a decrease in overall autism symptoms in a proportion of the children. However, as with most treatment programs these results do not apply to every child that receives PRT (for an overview on empirical support for PRT see Koegel, Koegel, and Brookman, 2003). For this reason it is of great importance that besides determining whether an intervention is effective, it may be even more important to determine how and in what way an intervention as PRT is effective and for which children.

In order to understand the mechanisms of effectiveness it is important to have optimal knowledge on the underlying cognitive and affective processes that contribute to the motivation for social initiative and to the quality of the social interaction. With this knowledge, we can identify building blocks of the ASD phenotype that can be influenced by treatment and use this knowledge to identify the subgroup of children that show a high response to treatment. Studies on cognitive and affective mechanisms that are considered relevant for emotion regulation and the regulation of social adaptability show that there

are considerable individual differences between children with ASD. It is important to study these individual differences as this knowledge can help in A) elucidating individual vulnerabilities in the social-emotional development and related individual differences in response to treatment and B) identifying how changes in cognitive and affective functioning relate to changes in ASD symptoms in response to intervention.

It is clear from parental report and clinical observation that children with autism show a high level of emotion regulation problems, sometimes react intense and highly anxious in situations that are stressful or otherwise, show the opposite, very bland affect in social interaction. However, thus far it has remained largely unclear to which extend these observable behaviors are related to underlying problems in affect regulation, as expressed in a potential imbalance in affect, reflected in heart rate, skin conductance and cortisol responsivity, and the cognitive skills of these children to be able to regulate this arousal. These are core mechanisms in behavior regulation and social adaptivity. This study is innovative in the use of such objective affect regulation measures, which can provide insight into affect development beyond the limited information that can be gained from qualitative measures, self-report or reflection in young children with ASD.

Besides studying this in children with autism, it is of great importance to include their parents in this study and to look more closely at the parent-child interactions as this may highly impact the development of affect regulation in children. In other words, this study also focuses on the quality of attunement between parent and child.

Study objective

This study has two main objectives. One objective is to investigate which cognitive and affective mechanisms can be influenced through treatment which leads to improved social functioning. We will use a carefully selected set of behavioral, neuropsychological, and neurobiological tests focusing on measures related to the functioning and regulation of affective arousal. Specifically, concerning these underlying mechanisms of social functioning, we hypothesize that cognitive and neurobiological factors that contribute to the regulation of behavior and emotion are related to the effectiveness of treatment (i.e. mediating the effect of PRT on social adaptation) and thus will be influenced by PRT. Which components moderate this effect is topic of this study.

The second objective of this study is to define the parent and child characteristics that predict changes in functioning of children with ASD, i.e. the effectiveness of treatment. The focus lies not necessarily on proving effectiveness of treatment for ASD, previous research has already proven this. Therefore, the proposed research is not an effect study, but a study on the applicability (for which children and parents PRT is most effective) and the underlying working mechanisms (on which domains PRT has an effect). Concerning

the predictors of treatment efficacy, our hypothesis is that factors that contribute to the regulation of behavior and emotion play an important part in the effectiveness of treatment and are thus predictors for PRT efficacy. An important factor in this is the parent-child relationship. For example, the way parents regulate stress is of influence on the quality of the interaction between parent and child and is thus of influence on the social behavior and emotions of the child.

These two main objectives can be divided into two sub studies, one focusing on the child characteristics and the other on the parent characteristics.

See protocol pages 15 and 16.

Study design

The study will be conducted at the Centre for Autism, where PRT is already part of the clinical activities. We would like to stress that this study is an evaluation of a standard clinical protocol at the Centre for Autism. Therefore, this study will not affect the regular procedure of clinical care, and there are no costs involved for participants except for those that are part of the regular clinical care. The design of the study is a longitudinal, randomized controlled trial (RCT), in which half (n=30) of the children with ASD will receive PRT treatment during the study and the other half (n=30) will form a waiting list condition and will receive PRT after the study. The maximum waiting time is 6 months, which corresponds the typical waiting list time at the Centre for Autism. Assignment to either the PRT condition or the waiting list condition, will be randomized alternately.
Again, the waiting list condition is needed to relate any changes in social functioning, ASD symptoms and affect regulation in the ASD group specifically to PRT. A non-clinical control group (i.e. boys and girls from the general population) is needed to test areas of deficits, dysfunction and development in the children with autism as compared to typically developing peers.

Intervention

Children with autism and their parents will all (eventually) receive PRT. The duration and amount of treatment sessions is equal for all participants, i.e., children and their parents will go to the Centre for Autism once a week during a period of 6 months.
The phasing is different for all groups. The Centre for Autism has a waiting list of 6 months for the start of PRT, so that some families will start PRT later than others. This waiting list allows us to compare children that have had the PRT to children that have not received PRT yet.

PRT is recommended for certain children and their families after careful deliberation in the diagnostics meeting at the Centre for Autism. PRT is

particularly suited for children who have developed little or no speech, taking into account the load for, and the capacity of the parens (are they Dutch, or English speaking, do they have the time to invest in the PRT etcetera). After this first screening, the therapist will set up a treatment plan in which, in consultation with parents, the goals of the PRT will be recorded. These goals will be fit to meet the treatment demand that parents have, and taking into account tthe needs and abilities of the child.

Study burden and risks

Benefits
Healthy control children plus their mother will receive a travel allowance for both visits to Leiden University. In addition, parents will receive a gift card with a value of 30 euro*s after the first visit, and a gift card of 50 euro*s after the second visit. The children will receive a small present at the end of each session as gratitude for their cooperation in the study.
The children with autism plus their parents, both in the PRT and waiting list condition will not receive a travel allowance or financial reward, because this study is incorporated in the regular appointments at the Centre for Autism and does not require them to come to the centre more often than usual. The children will receive a small present at the end of each session.

Burden
There are no risks involved in the proposed study. Children and parents from the ASD group already have received the permission to start the PRT training at the moment they enroll in the study. In addition to the PRT training, 3 measurement moments of in total 9 hours are added, in which both the mother and the child are tested (i.e. parallel).
Children and mothers in the control group will not be asked to participate in the PRT and will have only 2 measurement moments, the second time point being 6 months after the first. In total, a time investment of 7 hours is asked from the healthy control group, in which both the child and the mother are tested.
In reward, parents will receive travel allowance and a gift card with a value of 30 euro's for the first visit and of 50 euro's for the second visit. Also, children will receive a small present at the end of each session as gratitude for their cooperation in the study.
In addition, if requested by their clinician, parents can give permission to send the results on the cognitive performance of their child to the clinician.

Group relatedness
A typically developing group of children plus their mother is needed in order to quantify change in social behavior over time, i.e. does the treatment group show a change in deviation from typical development. At baseline and follow-up we will quantify to what degree social behavior in ASD children is different from typically developing children. By comparing these deviation scores from baseline to follow-up, we will be able to assess to what degree children with ASD have improved. Data from typically developing children and their parents in

also needed to identify 1) responder profiles, i.e. a profile of strengths and weaknesses in the ASD group as compared to a typical group and 2) calculate deviations in affect regulation mechanisms in the ASD group over time as compared to normal development.
In order to assess whether changes in affect regulation or social behavior are the result of PRT, a clinical control group is needed, consisting of ASD children (and their parents) who are on the waiting list for PRT during this study.
Choosing this specific age group (three to six year olds) is crucial to this study because 1) it is of great importance to study the mechanisms of social and emotional functioning whilst they are still in development and susceptible for positive influences through treatment and 2) because treatment should start as early as possible since studies have shown that this will benefit the treatment outcomes significantly.

General Remark
It should be noted that a unique aspect of this study is that we incorporate not only the performance on a cognitive level, but also underlying affective mechanisms of emotion regulation processes in a population that experience profound difficulties in this area. Because of this multi-level approach, the list of measurement instruments is quite extensive. Therefore, while selecting the measurement instruments for this study, great care was given to the suitability of the tasks for this specific target group and the healthy control children. Besides considering the age range, the weak language development and the restricted attention span was taken into account while selecting appropriate measurement instruments. Therefore, the tasks that are selected require, for the most part, a non-verbal or motor response from the children. The instruments that ask a cognitive performance are administered alternately with tasks that do not, i.e. tasks that require children to watch movies for example. In addition, there is no overlap between all the measurement instruments, and all tasks measure a unique aspect with regard to answer the research questions.

Conclusion
In summary, we are convinced that the investment that we ask from the children and their parents is well balanced. We ask a smaller time investment from the control group than we ask of the ASD groups and we provide benefits both financially and in reporting back to the parents if needed. We believe that the time and effort we ask from children and parents outweighs the potential insights that the research can yield.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

General inclusion criteria include age between 3 and 6 years old, voluntary participation, Dutch or English speaking and a signed informed consent from parents or official caretakers. For the ASD groups additional inclusion criteria are an independent clinical diagnosis of autism according to the DSM-IV criteria that will be confirmed with an ADI-R and ADOS at the start of this study, intelligence quotient above 50, no neurological condition (i.e. epilepsy), severe head trauma with loss of consciousness and / or metabolic diseases.

Exclusion criteria

General exclusion criteria are:
- IQ < 50
- Lack of comprehension of the Duch or English language by parents and/ or child
- History of neurological conditions or head injury with loss of consiousness for children, and/ or metabolic diseases

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-07-2013
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	24-04-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
Other	ECPW-2012/042
CCMO	NL41221.058.13