

Tandem study: Theraplay in children with autism spectrum disorder and their parents.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20704

Source

Nationaal Trial Register

Brief title

Tandem study

Health condition

Autismspectrumdisorder (ASD)

Sponsors and support

Primary sponsor: 1) Stichting Korczak Foundation for Autism and Related Disorders, 2) Stichting tot Steun VCVGZ, 3) SARR expertise centrum autisme, Youz kinder- en jeugdpsychiatrie, Parnassia Groep

Source(s) of monetary or material Support: 1) Stichting Korczak Foundation for Autism and Related Disorders, 2) Stichting tot Steun VCVGZ, 3) SARR expertise centrum autisme, Youz kinder- en jeugdpsychiatrie, Parnassia Groep

Intervention

Outcome measures

Primary outcome

Is Theraplay an effective treatment for children with ASD and what is the effect of treatment with Theraplay on their parents?

Secondary outcome

- 1) Does Theraplay improve the parent-child relationship between children with ASD and their parents?
- 2) Does Theraplay lead to a decrease in psychiatric problems, such as internalizing and externalizing problems and ASD specific traits, in children with ASD?
- 3) Does Theraplay provide a decrease in both physical and mental parental distress in parents of a child with ASD?
- 4) Is head hair cortisol a suitable biomarker for measuring the effectiveness of Theraplay?

Amendment on the Tandem study: IMDAD

- 5) Are immunological and microbiome assessments suitable biomarkers of chronic stress in children with ASD and their parents?
- 6) Are these immunological and microbiome biomarkers suitable predictors of therapeutic effectiveness?
- 7) Does Theraplay reduce the biological effects of stress?

Study description

Background summary

A randomized study with control group (RCT). The general research question is whether Theraplay is an effective treatment method for children with ASD and what the effect is of Theraplay treatment on their parents? The general research question will be answered through sub-questions: 1) Does Theraplay improve the parent-child relationship between children with ASD and their parents? 2) Does Theraplay lead to a decrease in psychiatric problems, such as internalizing and externalizing problems and autism specific traits in children with ASD? 3) Does Theraplay provide a decrease in physical and mental stress in parents of a child with ASD? 4) Is head hair cortisol a suitable biomarker for measuring the effectiveness of Theraplay?

Study objective

Main question:

Is Theraplay an effective treatment method for children with ASD and what is the effect of treatment with Theraplay on their parents?

Prior RCTs proved that Theraplay leads, among other things, to a decrease in internalizing problem behavior and language disorders in children. Theraplay improves the clinical functioning of the child and the pedagogical skills of parents. Theraplay has not previously been studied in a RCT as a treatment method for children with ASD and their parents. The hypothesis is that Theraplay is suitable for children with ASD and their parents, due to

the directive nature of the play intervention and the increase in the connection between parents and child. Frequent co-morbid problems such as developmental delays, intellectual disabilities and speech and / or language impairments are not an exclusion criterion. Parents with a child with ASD experience more stress within the parent-child relationship. Parental stress can cause problem behavior in children. This creates a vicious circle. In addition, (chronic) stress in parents can result in mental and physical complaints and ultimately in illness. Theraplay allows parents to better understand their child with ASD. This will reduce parental stress. The child feels better understood, so that problem behavior decreases with the child.

Sub-questions:

1) Does Theraplay improve the parent-child relationship between children with ASD and their parents?

Early intervention has been proven effective for children with ASD and their parents. It improves the social interaction between mother and child. Other interventions that have been investigated through RCT have already shown this. It is also known that the parental distress reinforces problem behavior of children with ASD more than the other way around. The hypothesis is that the directive play intervention Theraplay, based on the attachment theory, can ensure that parents understand their child better so that they can respond more appropriate to the physical and mental needs of their child. A child who experiences that his parent adequately deals with his / her emotional and physical needs will show less problem behavior. Less problematic behavior in a child leads to a decrease in both physical and mental parental stress. As a result of a decrease in problem behavior in the child and parental stress, a more positive way of contact between the child and the parent can occur.

2) Does Theraplay lead to a decrease in psychiatric problems, such as internalizing and externalizing problem behavior and ASD specific traits, in children with ASD?

It has been proven that children with ASD often have several problem behaviors besides their specific ASD characteristics. This can be internalizing (inwardly) problem behavior such as social withdrawal, anxiety, depression and psychosomatic complaints. Or, this can be externalizing (outward-facing) problem behavior such as aggression, over-active or border-seeking behavior. Theraplay is proven effective in reducing internal- and externalizing problem behavior, behavioral and speech / language problems in children with developmental and / or behavioral problems. The hypothesis is therefore that Theraplay can provide a decrease in psychiatric problems, such as internal and / or externalizing behavior and ASD specific traits in children with ASD.

3) Does Theraplay provide a decrease in both the physical and mental distress in parents of a child with ASD?

It has been proven that parents of a child with ASD often have chronically increased stress compared to parents of a child without ASD. Chronic increased stress can lead to medical problems with increased morbidity or mortality. The hypothesis is, that through Theraplay parents learn to attune in to their child with ASD. They learn to understand their child better, so that their daily parenting tasks will be easier than before. This can lead to a decrease in mental and physical parental distress. In addition, the child will feel better understood, and because of this, the child's problem behavior will decrease. A decrease in problem behavior in the child can also lead to a decrease in mental and physical parental distress.

4) Is head hair cortisol a suitable biomarker for measuring the effectiveness of Theraplay? It has been proven that parents of a child with ASD have abnormal short-term (minutes-1 day) cortisol profiles. However, longer term (1 month for head hair cortisol) cortisol determinations have not previously been determined as a follow-up measure to compare two treatments. Furthermore, the head hair cortisol is also used in answering another sub-question. For example, it is known that extremely elevated cortisol levels (eg in Cushing's syndrome) lead to abdominal obesity, diabetes, dyslipidemia, hypertension, cardiovascular disease and depression. In addition, head hair cortisol can serve as a measure of the quality of the parent-child interaction. Recent studies showed the relationship between head hair cortisol of parents and obesity within their child, as well as the relationship between increased head hair cortisol in children with ASD and more anxiety symptoms. The hypothesis is that head hair cortisol can be seen as a biomarker for the effectiveness of Theraplay. Head hair cortisol is a measure of physical and mental stress. Physical and mental stress should be reduced by Theraplay. With decreasing physical and mental stress, one expects a decrease in the values of the head hair cortisol. If, after obtaining Theraplay, a decrease in head hair cortisol is found, head hair cortisol can serve as a biomarker for the effectiveness of Theraplay.

Amdement on the Tandem study: IMDAD. In which 50 children and their parents in the Tandem study will participate by donating a blood, feaces and saliva sample during start and end measures of the Tandem study.

5) Are immunological and microbiome assessments suitable biomarkers of chronic stress in children with ASD and their parents?

Previous studies show that long-term exposure to stress affects the immune system and microbiome. Chronic stress can lead to increased glucocorticoid resistance. This increased resistance is associated with increased levels of inflammatory factors in the blood and saliva, which indicates activation of the immune system. Although immune parameters appear to be related to stress, it is not known which of these immune parameters are good biomarkers of stress in children with ASD and their parents. It is hypothesized that elevated inflammatory immune parameters can be seen as a biomarker for psychosocial stress. With elevated inflammatory immune parameters, the psychosocial stress of parents is also expected to be high. If immune parameters are strongly related to the psychosocial stress reported by parents and / or to the scalp cortisol, then these immune parameters may serve as a biomarker for psychosocial stress. In addition to changes in the immune system, stress also appears to lead to changes in the bacterial composition in the microbiome⁶⁵. A study in mice showed that the administration of the bacterium *Lactobacillus rhamnosus* reduced anxious behavior in response to stress. A recent study in humans found that in people with depression, the bacteria *Coprococcus* and *Dialister* were less common. As multiple studies show associations between the amount of specific bacteria and stress, the microbiome is expected to serve as a biomarker for psychosocial stress in children with ASD and their parents. In addition, the interaction between parents and children will be examined: it will be examined whether the immune system and the microbiome of parents and children are related and whether immunological and microbiome biomarkers of parents are related to stress in the child.

6) Are these immunological and microbiome biomarkers suitable predictors of therapeutic

effectiveness?

Previous studies show that long-term exposure to stress affects the immune system and microbiome. The microbiome and immune system appear to be related to physical and mental health. Currently, there are no controlled randomized studies in children with ASD and their parents that use biological, physical and mental outcome measures. In addition, there are no biomarkers available yet that predict which children or parents will benefit most from a specific treatment. The hypothesis is that immunological and microbiome assays are associated with chronic stress on an individual level.

7) Does Theraplay reduce the biological effects of stress?

Previous research shows that parents learn to understand their child with ASD better through Theraplay. Since a reduction of stress is expected through Theraplay, and stress is associated with the immune system and microbiome, it is expected that Theraplay will also lead to a reduction in the biological effects of stress.

Study design

6 years

Intervention

Theraplay versus treatment as usual (mainly psycho-education and parental guidance, other therapies such as medication possible)

Contacts

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Eligibility criteria

Inclusion criteria

1. Primary diagnosis of ASD (children with developmental delay, intellectual disability or other co-morbid psychiatric problems are included)
2. Age of the child is between 3 and 6 years.
3. Child and parents can understand and speak Dutch without the need for an interpreter.

Exclusion criteria

1. Starting new psychopharmaceuticals within 3 months prior to participation in the study. Psychopharmaceuticals that have been used for a longer time can be continued.
2. Following another psychological treatment by the child elsewhere during participation in the study.
3. Having followed any type of play therapy or play based intervention by child and / or parents, prior to participating within this study.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	19-11-2018
Enrollment:	150
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date: 07-02-2019

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	NL7534
Other	METC : P18.080/Dj/dj (METC LUMC file number)

Study results