Tandem study: The effectivity of Theraplay on children with autism spectrum disorder and their parents.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52655

Source
ToetsingOnline

Brief title
Tandem study

Condition

- Other condition
- Developmental disorders NEC

Synonym
autism spectrum disorder AND parental mental and physical distress

Health condition

fysieke en mentale stress bij ouders van een kind met ASS

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia (Den Haag)
Source(s) of monetary or material Support: Stichting Korczak Foundation for Autism and Related Disorders: 250.000 euro Stichting tot Steun VCVGZ: 250.000 euro Vrienden Parnassia Groep 120.000

Intervention

Keyword: Autism Spectrum Disorder, Children, Parents, Theraplay

Outcome measures

Primary outcome

Is Theraplay an effective treatment method for children with ASD and what is

the effect of a treatment with Theraplay on their parents?

Secondary outcome

The effectiveness of Theraplay on 1) the parent-child relationship between

children with ASD and their parents, 2)

psychiatric problems, such as internalizing and/or externalizing behavioural

problems and autism specific traits within

the child, 3) parental mental and 4) physical distress, 5) the use of hair

cortisol as a potential biomarker for treatment

effectiveness, 6) a decrease of the immunological and microbiological

consequences of chronic stress 7) the use of

immunological and microbiome measurements as biomarkers of chronic stress 8)

the use of immunological and

microbiome measurements as biomarkers of treatment effectiveness.

Study description

Background summary

Evidence-based treatment methods based on randomized controlled trials for children with ASD are scarce. Moreover, there is hardly any research regarding interventions for children with ASD in which the mental and physical health of their parents is included as a treatment goal. Chronic distress in parents having a child with ASD, can lead to severe mental and physical health problems, with increased mortality as a consequence. Furthermore the use of a biomarker for treatment effectiveness in children with ASD is not available.

Study objective

In this study the three-dimensional approach is central in the treatment. The treatment is focused on 1) the child with ASD, 2) the parents, 3) the parent-child relationship, instead of the current one-dimensional approach. Instead of treating parents as an extended version of their child, we take the health of the parents as a treatment goal and as an essential factor in the well-being of the child with ASD.

Study design

Randomized controlled trial (RCT) in which one group will receive Theraplay and the other group will receive treatment as usual (TAU).

Intervention

Theraplay is a directive play intervention based on the attachment theory. It is a semi structured treatment method. Before every Theraplay trajectory a MIM-NL-II trajectory is performed. This is a structured parent-child observation specifically developed to set the goals within the Theraplay trajectory. In response to the MIM-NL-II the content of the Theraplay sessions will be composed. The Theraplay goals are discussed with the parents during the MIM-NL-II feedback session. Followed by a parent session in which parents receive information about translating the goals of the MIM-NL-II to the Theraplay sessions. Moreover, parents undergo several Theraplay activities in preparation for the Theraplay trajectory. Thereafter parent and child have a weekly Theraplay session of approximately 45 minutes. The duration of the sessions can vary, depending on the concentration span of the child. After every three Theraplay sessions a parent feedback session is planned in which the goals of the Theraplay trajectory are evaluated. Besides Theraplay, also psychoeducation and parent guidance is provided during the parental sessions. Parents and the Theraplay therapist decide during the parent feedback sessions whether the Theraplay trajectory will be continued or finished depending on the

goals being achieved. An average Theraplay trajectory lasts 26 sessions, approximately 8 months.

Treatment as usual (TAU) consists of psychoeducation regarding ASD followed by parent guidance sessions. During the guidance sessions parents learn to apply the information from the psychoeducation regarding their child with ASD. Additionally other forms of treatment, such as pharmacotherapy can be applied. TAU will also have a duration of on average 8 months.

See the researchprotocol for an extended clarification of the intervention including references at: Treatment of subjects

Study burden and risks

Participants of the study receive treatment in one of the two research-groups: Theraplay or TAU, both of similar
duration. Three times during the researchperiod of one year, measurements are made. Namely, before start of the
study (T0), 6 months (T1), and 12 months after start of the study (T2). During the visit, measurements of the child and
parents consist of: video-observations (free play and an ADOS-2), physical measurements (height and weight) and
hair-cortisol which will be obtained by cutting of a small piece of hair on the back of the head. Parents will undergo
some extra physical measurements: waist circumference, blood pressure and simultaneously heartrate. Prior to these
measurements parents fill in a set of questionnaires at home and a blood sample is taken. In addition to these
measures, before the start of the study (T0) and after start of the study (T2), a small quantity (size of a marble) of stool
and salvia (1 ml) will be obtained from 50 children and their parents. The teacher or day-care facilitator of the child will
complete two questionnaires about observed behaviour of the child. At last, prior to every therapy session parents
complete two short computerised questionnaires, which will take up to a maximum of 10 minutes each time. In our
opinion participating in this study will not pose evident risks upon the participants. It is mainly a time-investment we ask
from the parents and the children to fill in questionnaires by parents and to perform measurements on the parents and
their child.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

1. Primary diagnoses of autism spectrum disorder. Children with a developmental delay, mental retardation or co-morbid psychiatric disorders, which are often found in children with autism, can be included.
2. Children aged from 3 to 6 years old.
3. Child and parents understand Dutch and can communicate in Dutch without interpreter.

Exclusion criteria

1. Start of new psychiatric medication within three months before the start of the study. Medication use for longer periods can be continued. Medication can be stopped during the study.
2. Following another concurrent psychological treatment at the same time elsewhere.

3. Child and/or parent(s) have followed any kind of play therapay or play intervention in the past.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-11-2018
Enrollment:	450
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	15-11-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Not approved

Date:	08-10-2019
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	11-11-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	15-01-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	20-04-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	21-06-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	07-06-2024
Application type:	Amendment
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
CCMO	NL63780.058.18