Intervention SENSory regulation Early life

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The aim of this project is to investigate a parent-mediated treatment method targeting sensory processing difficulties thereby improving the emotion regulation difficulties and quality of life of the child and its family.

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

Summary

ID

NL-OMON57172

Source
ToetsingOnline

Brief title
iSENSE

Condition

- Developmental disorders NEC

Synonym
Sensory atypicalities; Sensory processing difficulties

Research involving
Human

Sponsors and support

Primary sponsor: GGZ instellingen / Psychiatrische Ziekenhuizen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Early intervention, Parent-child interaction, Sensory Processing Difficulties

Outcome measures

Primary outcome

• Emotional regulation capacities of the child using The Emotion Dysregulation Index (EDI) (Samson et al., 2013).

• Quality of life of the child using the Pediatric Quality of Live Inventory (PedsQL) (Varni et al., 1998).

Secondary outcome

• Adaptive functioning using the Vineland Screener 0-6 years (Scholte et al., 2008) is completed by parents during the intake process and two times more, to asses a short-term and long-term adaptive functioning level of the child.

• Sensory processing difficulties using the Sensory Profile-NL-2 (SP-NL-2) (Dunn, 2002).

• Parental burden based on the Opvoedingsbelasting Vragenlijst (OBVL) (Vermulst, Kroes, De Meyer, Nguyen, & Veerman, 2015).

• Quality of life of the parents using the Pediatric Quality of Live Inventory Family Impact Module (PedsQL-FIM) (Varni et al., 1998).

• Parental sensitivity and co-regulation using the Parent-Infant/Toddler Coding of Interaction - Preschool (PInTCI-P) (Pijl et al., 2018).

• Last, parental level of satisfaction is rated on a 5-point Likert Scale short-term post-intervention, using a 20-item custom made questionnaire.

Study description

Background summary

Clinical observations and scientific research show that parents referred to specialized mental health care often ask professional support regarding sensory processing difficulties of their young child. It is well established that sensory processing difficulties can have a profound negative impact on a child*s functioning (Posar, 2018) which may continue later on in life. While increasing the risk for emotional regulation problems, social withdrawal and impaired quality of life, it also effects participation in society such as work and leisure activities (Benen Demchick, Goldrich Eskow, & Crabtree, 2014; Costa-López, 2021; Schaaf, Toth-Cohen, Johnson, Outten, & Benevides, 2011). Children may be hyper- and/or hyporeactive to sensory stimuli or both at different times, which makes it difficult for parents to understand and interpret their child*s signals and respond adequately. Importantly, at this point no evidence-based treatments are available that focus on young children with sensory processing difficulties.

Study objective

The aim of this project is to investigate a parent-mediated treatment method targeting sensory processing difficulties thereby improving the emotion regulation difficulties and quality of life of the child and its family.

Study design

Given the expected heterogeneity in our study population, an experimental single-subject design is used in this study (A1-B-A2 design) (Backman et al., 1997) to investigate this intervention.

Intervention

The intervention consits of an e-learning, parent groups, and individual parent-child sessions (home visits).

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefits, and group relatedness: Participants (parents/caregivers and children) are expected to benefit from the treatment. The risks associated with participating in the study were considered negligible and the burden associated with participation was estimated to be low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Age between 0-7 years old.
-Meeting the decision criteria need for highly specialized mental health care, based on the Decision
Tool of Karakter Young Child Center.
-Evident sensory processing difficulties, with hyperreactivity or both hyper- and hyporeactivity to
sensory stimuli, based on the information collected during the intake process and the SP-NL-2
(Dunn, 2002) questionnaire and interview, the latter two completed within 3 weeks after completion
of the intake process both by a member of the research team.

Exclusion criteria

-No completed or ongoing treatment at Karakter for parents/primary caregiver or child
-Children with only hyporeactivity to sensory stimuli are excluded, due to the use of habituation
techniques.
-Unable - although support¬ - to respond to questions (parents)
-Insufficient mastery of Dutch language (parents)
-Trauma-related disorders/complaints for which trauma treatment is directly indicated in the child
-Attachment problems that meet the classification criteria for an attachment disorder according to
the Diagnostic and Statistical Manual of Mental Disorders-5 (DSM-5).

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2024
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	15-10-2024
Application type:	First submission
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	NL85666.091.23