MASTER: A study on the effects of a parent training for toddlers with emotion dysregulation and an increased likelihood of developing ADHD

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Ethical review	Not approved
Status	Pending
Health condition type	Developmental disorders NEC
Study type	Interventional

Summary

ID

NL-OMON56546

Source
ToetsingOnline

Brief title
MASTER

Condition

- Developmental disorders NEC

Synonym
Emotion dysregulation; emotion problems

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: ADHD, Emotion regulation, Prevention, Training

Outcome measures

Primary outcome

Primary intervention parameter: pre-post training change in toddler*s emotion dysregulation as measured with EDI-YC.

Secondary outcome

Secondary outcome measures include child and parent functioning as well as parent-child interaction measures. Moreover, we will explore possible mitigating effects on ADHD symptoms at 4.5 and 6.5 years of age as measured with the CBCL and the ADHD section of the DIPA diagnostic interview. Additionally, we will investigate whether changes in ED symptoms in the one parent, predict changes in ED in the other parent.

Study description

Background summary

Children of parents with mental Illness (COPMI) have an increased risk of developing mental health problems themselves. Several mechanisms contribute to this intergenerational transmission of mental health problems. One of the most prevalent mechanisms are intense emotional interaction patterns in which the parent does not succeed in regulating his/her own emotions and those of the child. Instead, the parent may overreact (expressing intense emotions, i.e. yelling, crying, panicking) or underreact (ignoring the child while present, leaving the child alone). These emotional dysregulated (ED) interaction patterns are more common in parents with mental health problems and often begin in infancy or toddlerhood when the pre-verbal child communicates primarily by expressing emotions. Parent-child interaction interventions have proven to be effective in alleviating these ED-interaction patterns. Moreover, several

studies reported positive longer-term cascading effects for child development, parental quality of life and family functioning. In the Netherlands, parent-child interaction interventions in primary care are available for COPMI of 0-1 year and 4 years and older, but not for COPMI of 2-3 years of age (https://richtlijnenjeugdhulp.nl/kopp/inzetten-van-interventies/overzicht-van-interventies/). Only after problems have escalated, which is particularly risky for this group, intervention can be offered in specialized care. Therefore, we have developed MASTER: a parent-child interaction training for 1st line care for COPMI of 2 and 3 years old. For the current study, the training will be offered to parent(s) with ADHD that have a toddler that frequently expresses intense emotions. ED parent child interactions are particularly common in this target group and may contribute to the toddlers* risk of developing ADHD or related problems. As such, early intervention strengthening emotion regulation is expected to improve emotion regulation and potentially mitigate the development of (severe) ADHD.

Study objective

Primary intervention objective: to evaluate change in emotion dysregulation in at-risk-for-ADHD toddlers (24-36 months) during the 8-week intervention period of MASTER compared to the 6-week baseline (control) period. Secondary intervention objectives: to evaluate (child, parent and intervention predictors of) change in secondary outcomes during the 8-week intervention period compared to the 6-week baseline (control) period; to evaluate (child, parent and intervention predictors of) change in the primary outcome and secondary outcomes at follow-up (2 months and 1-year). Primary mitigating objective: to evaluate whether the degree of ADHD symptoms at 4.5 and 6.5 years of age is different for MASTER-participants compared to that of matched participants in the prospective cohort study ROAD; Secondary mitigating objective: to evaluate whether the prevalence of a research diagnosis ADHD at 4.5 and 6.5 years of age is different for MASTER-participants compared to that of matched participants in the prospective cohort study ROAD; Tertiary objective: to evaluate (child, parent and intervention predictors of) change in the primary outcome and secondary outcomes at 4.5 and 6.5 years of age.

Study design

An 8-week pre-post intervention design with a 6-week baseline period is used to evaluate change in the outcomes of interest. Follow-up assessments take place at 2 months and 1 year after the post training assessment. 1:1 randomization is used to determine which parent participates in the training. In addition, 1:1 randomization is used to determine the training delivery method (MASTER-1 or MASTER-2). Non-randomized, matched-sample comparisons will be made with participants from a prospective cohort study (ROAD) to evaluate long-term outcomes at 4,5 and 6,5 years of age.

Intervention

MASTER aims to improve the toddler*s emotion regulation problems through strengthening parental emotion regulation knowledge and skills. The MASTER training is designed for 1st line care, being relatively short (8-sessions) and delivered by University of Applied Sciences (HBO in the Netherlands) level trained therapists. MASTER is based on the most important elements of effective treatments in parent-based trainings for older children: practice-based, stimulating positive parent-child interactions and increasing parental emotional communication and regulation skills. Two versions of the training have been developed (MASTER-1: parent-therapist sessions with practices for the home situation; MASTER-2: parent-child-therapist sessions with practices with guidance of the therapist).

Study burden and risks

Participants receive regular forms of therapy and participate in interviews/ questionnaires. The risks are negligible and the extra burden is minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Child's age at enrollment 24-36 months;
• Child has a substantially elevated level of emotion dysregulation (normatively highest 30%) as measured with the EDI-YC (>=8) by at least one of the parents;
• At least one of the biological parents has been diagnosed with ADHD and is still experiencing clinical levels of ADHD symptoms or is under active treatment for the ADHD symptoms.
• Both parents are willing to participate in the intervention.

Exclusion criteria

The following exclusion criteria will applied:
• Presence of emotion regulation problems that are so severe (ED-YC >= 19, which represent scores more than 2 SD*s higher than the general population) that complex developmental and behavioral problems are present. The child is better helped with more intensive specialist care;
• Parent(s) suffer(s) from a disorder that severely limits the capacity to take part in the intervention, e.g. meeting DSM-5 criteria for schizophrenia, psychosis, or severe depression (as indicated by a score of >= 20 on the PHQ-9). In this case the family is better helped when the parent is referred to specialized care;
• Insufficient parent capacity as caused by one or more of the following problems: financial uncertainty, housing, health problems. The family is better helped by a broader approach provided by the municipality;
• The presence of a concerning parenting situation where there is a supervision order for the child or a trajectory for a supervision order is ongoing;
• Current treatment in specialized mental healthcare because of concerns regarding the child*s development or attachment to parents

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2024
Enrollment:	134
Type:	Anticipated

Ethics review

Not approved

Date:	24-01-2024
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL85712.000.23