Two-day EMDR treatment programme for parents of MPS III patients

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22550

Source
Nationaal Trial Register

Brief title
EMDR for parents

Health condition

Posttraumatic stress (disorder)

Sponsors and support

Primary sponsor: Amsterdam UMC, location AMC
Source(s) of monetary or material Support: Amsterdam Public Health research institute (Mental Health), Kinderen en Kansen

Intervention

Outcome measures

Primary outcome

Posttraumatic stress symptoms measured by the PTSD check List for DSM-5 (PCL-5) will be used as primary outcome to assess the effectiveness of the treatment programme compared to the waiting-list condition.

Secondary outcome

Secondary outcomes are outcomes on the Brief Symptom Inventory (BSI) that measures psychopathology in general, the Opvoedingsbelastingvragenlijst (OBVL) that measures parental stress, and the Distress Thermometer for Parents (DT-P) that measures everyday problems in parenting.

Study description

Background summary

Parents of mucopolysaccharidosis type III (MPS III) patients frequently face traumatic events related to the progressive course of the disease. A high percentage (22%) of these parents meet the criteria for post-traumatic stress disorder (PTSD), compared to 3.8% in the general population. PTSD can be effectively treated by Eye Movement Desensitization and Reprocessing (EMDR), traditionally offered in multiple sessions over weeks or months. However, this is time consuming and may thus prevent participation of parents as they are often overburdened. To overcome this barrier and provide necessary treatment, a short and more intensive treatment programme by a paediatric expertise centre may be effective. This pilot study focuses on the effectiveness of a two day EMDR treatment programme for parents of MPS III patients in reducing posttraumatic stress symptoms and psychological comorbidity (psychopathology in general, parental stress, and everyday problems in parenting).

Study objective

Parents who receive the two-day EMDR treatment will report significantly lower trauma scores and psychological comorbidity scores post-treatment compared to the wait-list group.

Study design

Parents will complete online questionnaires as baseline measurement before randomization (T0). Questionnaires are also completed two weeks (T2) and three months post-treatment (T3) in the intervention group and after 6 weeks in the waiting-list group.

Intervention

Parents are randomly assigned to the EMDR treatment or a waiting-list. For parents in the intervention condition an intake session (1 hour) consisting of a semi-structured interview will be scheduled. The two-day EMDR treatment programme will start within one week after the intake session and has a total duration of 6 hours (4 x 1.5 hour EMDR sessions). There will be one week between the first and second treatment day (or a maximum of two weeks if one week is not realisable for the parent).

Contacts

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Eligibility criteria

Inclusion criteria

- An increased score (moderately or higher) on one symptom in each cluster (B, C, D or E) or met 3 of the 4 PTSD criteria (one B symptom, one C symptom, two D symptoms and two E symptoms) measured by the PTSD Check List for DSM-5 (PCL-5) or an increased total score (>24) on the PCL-5.
- Being motivated for a short, intensive EMDR treatment programme.
- Parenting a child with MPS III under treatment by a metabolic paediatrician in het Emma Children’s Hospital/Amsterdam UMC.
- Having sufficient knowledge of the Dutch language to complete the assessments.
- Willingness to give a written informed consent in advance.

Exclusion criteria

- Major interfering acute medical or psychiatric condition, such as psychosis, substance dependence or high risk for suicide.
- Insufficient fluency of the Dutch language.
- Receiving psychological (trauma) treatment by another therapist at the same time.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2020
Enrollment:	24
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Plan description
N/A

Ethics review

Positive opinion

Date:	01-04-2020
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	NL8496
Other	METC AMC : METC 2019_119

Study results

Summary results
Outcomes of this study will be published in international scientific peer-reviewed journals.