Effectiveness of a two-day EMDR treatment programme for parents of MPS III patients: a randomized controlled pilot trial

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The primary objective is to assess the effectiveness of a two-day EMDR treatment programme compared to a wait-list condition for parents of MPS III patients, in reducing posttraumatic stress symptoms.The secondary objective is to assess the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON55023

Source
ToetsingOnline

Brief title
Two-day EMDR treatment programme for parents

Condition

- Other condition

Synonym
nvt

Health condition

Posttraumatische stress en psychologische comorbiditeit ten gevolge van het zorgen voor een ernstig ziek kind.

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Kinder en Kansen;Zeldzame Ziektenfonds;APH Mental Health

Intervention

Keyword: EMDR, mucopolysaccharidosis type III, parental support, posttraumatic stress

Outcome measures

Primary outcome

Post-traumatic stress (symptoms) will be measured by the PTSD Check List for DSM-5 (PCL-5). The PCL-5 is a self-reported questionnaire which assesses PTSD symptoms and is one of the most frequently used self-reported questionnaires for PTSD. The PCL-5 measures the 20 DSM-5 PTSD symptoms (divided in the clusters intrusions (B), avoidance (C), alterations in arousal and reactivity (D), negative alterations in cognitions and mood (E)) over the last week and is answered on a five-point Liker scale, ranging from 0 *not at all* to 4 *extremely*. A provisional PTSD diagnosis can be made by counting each item rated 2 (moderately) or higher and then applying the DSM 5 rules (one B symptom, one C symptom, two D symptoms and two E symptoms). The PCL-5 test scores demonstrated good internal consistency (* = .96), test*retest reliability (r = .84), and convergent and discriminant validity.

Secondary outcome

Psychological comorbidity will be measured by:

- Brief Symptom Inventory (BSI). BSI is a self-reported questionnaire (53

items) that measures psychopathology in general and consist of nine clinical scales: somatization, obsessive compulsiveness, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation and psychoticism measured on a five-point Likert scale (0 = *none* to 4 = *a lot*).
- Opvoedingsbelasting Vragenlijst (OBVL): The OBVL is a self-reported questionnaire (34 items) that assess parental stress that parents may experience in five dimensions: parent-child relation relationship, parental incompetence, depressed mood, health complaints and role restriction measured on a four-point Likert scale (1 = *incorrect* to 4 = *totally correct*).
- Distress Thermometer for Parents (DT-P): The DT-P is a self-reported questionnaire that assess parenting distress in parents of a chronically ill child. The DT-P consists of a thermometer score where parents are asked to rate their overall distress (0 = *no distress* to 10 = *extreme distress*). Distress is indicated as clinically relevant from a score *4. The thermometer is accompanied by a problem list (parents indicated whether they divided over six problem domains: practical, family/social, emotional, physical, cognitive, and parenting.

Study description

Background summary

Parents of mucopolysaccharidosis type II (MPS III of Sanfilippo syndrome) patients frequently face potentially traumatic events (e.g., receiving the initial diagnosis and experiencing the progression of the disease) followed by short- and long term stress responses. Exposure to such traumatic events can lead to a wide variety of psychological problems, such as posttraumatic stress, depression and anxiety. In addition, parents often suffer from anxious thoughts

about the future (such as the progressive course of the disease and death of their child). Recent research by our group on parenting a MPS III patient demonstrates high levels of anxiety and depression. The majority of the parents reported posttraumatic stress symptoms related to their child*s illness and 22% meet the criteria for Post-Traumatic Stress Disorder (PTSD), compared to 3.8% in the general population. It is known that stress symptoms in parents have a great impact on the well-being of the child, even on very young children and children with a cognitive disability. Therefore, treatment of the post traumatic stress symptoms of parents is important for both the well-being of the parent and the child. However, parents of children with a progressive life-threatening disease, such as MPS III, often do not get the specialized psychological care they need. Possibly because (1) psychologists in their own environment are mostly not all experts in this field of medical traumatic stress related to the progressive disease of their child, and (2) they are overburdened and therefore long-term therapies or weekly hospital visits are not sufficient. To overcome above barriers and offer sufficient help to parents and the patients, a short and more intensive psychological treatment provided by a pediatric expertise center is needed.

One of the most successful treatments for post-traumatic stress is 'Eye Movement Desensitization and Reprocessing' (EMDR). EMDR is traditionally provided in multiple weekly sessions divided over several months. We suspect however that this approach will lead to high drop-out rates in the already overburdened parents. Earlier studies showed that a short, intensive EMDR treatment in combination with physical exercise is effective in reducing PTSD symptoms in a short amount of time in other study populations (e.g., patients with severe PTSD). No research has been carried out yet to assess the effectiveness of a more intensive EMDR treatment programme for parental posttraumatic stress in the clinical practice of paediatric psychology. Within this research project, we want to assess the effectiveness of a short, intensive EMDR treatment programme (two days of EMDR sessions) on the post-traumatic stress symptoms and psychological comorbidity (psychopathology in general and parenting distress) in parents of MPS III parents. We believe that offering a two-day EMDR treatment programme will result in a clinically significant decrease in post-traumatic stress symptoms and psychological comorbidity in parents.

Study objective

The primary objective is to assess the effectiveness of a two-day EMDR treatment programme compared to a wait-list condition for parents of MPS III patients, in reducing posttraumatic stress symptoms.

The secondary objective is to assess the effectiveness of a two-day EMDR treatment programme compared to a wait-list condition for parents of MPS III patients, in reducing psychological comorbidity (psychopathology in general,

parental stress, and everyday problems in parenting).

Study design

The current study will use a *randomized controlled trial pilot design* with two arms: the intervention condition and the wait-list condition (6 weeks)to assess the effectiveness of the two-day EMDR treatment programme (see Figure 1). Both mothers and fathers will be invited by letter to participate in the study. If parents are interested in participating in the study, they will be asked to fill in online questionnaires at home (T0, pre-treatment) as baseline measurement and to screen for the inclusion criteria. Eligible parents (see section 4.2) will be randomly allocated to the intervention condition or the wait-list condition. For parents in the intervention condition an intake session (1 hour) consisting of a semi-structured interview will be scheduled 2 weeks after randomization. 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). Parents in the intervention as well as the wait-list condition will be asked to fill in online questionnaires at 6 weeks after the baseline measurement (T1, two weeks post treatment or post waitlist). In the intervention condition a follow up assessment will be scheduled at three months post treatment (T2, follow up). Parents in the wait-list condition can start with the treatment programme after the waitlist period of 6 weeks (also followed by measurements two weeks post treatment and three months post treatment). We have chosen to offer the treatment to parents in the wait-list condition directly after six weeks since EMDR is a treatment with negligible risks and we suspect that a waiting period of 6 weeks will keep parents motivated for the study. Moreover, it will minimize the period in which parents can exchange information with each other and thereby influence the outcomes. Both the intake session and EMDR therapy will be carried out at the Psychosocial Department of the Emma Children*s Hospital/Amsterdam UMC in a suitable consultation room.

Intervention

The therapists that provide the EMDR therapy are licensed master*s degree (clinical) psychologists and advanced EMDR practitioners, working at the Amsterdam UMC or de Bascule.

Intake session:
A standardized case conceptualization will be developed by the therapist and parent consisting of a hierarchy of disturbing and stressful memories of traumatic experiences or flash forwards (fears of the future that are experienced in the present) regarding the disease of their child. If an acute psychiatric condition appears to be present and a two-day EMDR treatment

programme seems not indicated, the therapist will refer the parent (if preferred) to more appropriate psychosocial/psychiatric support. Besides the EMDR therapist, a researcher (that is also a psychologist) or psychological intern will be present to take notes.

EMDR treatment:
EMDR treatment (4 x 1.5 hour divided over 2 days, see Table 1) will be offered by following the standard eight-phase protocol (that is also used as standard care) presented by De Jongh and Ten Broeke. There will be one week between the first and second treatment day (a maximum of two weeks if one week is not realisable for parents). During an EMDR session, the patient focuses on emotionally disturbing memories (image, thoughts, emotions and sensations) in brief sequential doses while simultaneously focusing on an external distracting stimulus (e.g., lateral eye movements). This process facilitates accessing the traumatic memory network so information processing is enhanced and new associations can be made between the traumatic memory and more adaptive memories and information. As result, the traumatic memory representation will be less intense and emotionally disturbing. Besides the EMDR therapist, a researcher (that is also a psychologist) or psychological intern will be present to take notes.

Important to note is that parents will be told at the last treatment day that they can call at any time if they need more psychological support before the end of the study.

Evaluation:
The researcher (not the therapist) will have a short telephonic interview with parents about how they experienced the treatment program, if they would recommend it to other parents, if they have suggestions for improvement, if the program was sufficient for them to relieve stress related complaints or if they need more psychological support. At last the researcher will explore if potential traumatic events related to the disease of their child occurred since the last treatment day.

Study burden and risks

Parents will spent approximately 7 hours in the Amsterdam UMC during participation in the study. Participation in the study is associated with negligible risks for parents. EMDR is proven to be a safe, well tolerated treatment, even for very vulnerable patients. EMDR will be offered by qualified therapists and is part of standard care in the Emma Children*s Hospital. As with any form of psychotherapy, there may be a temporary increase in distress. Subsequent to the treatment session, the processing of information may continue and dreams, memories or feelings may emerge. The experience is however that EMDR is very effective in decreasing stress levels immediately and after the session. Earlier studies have shown that both an intensive eight-day EMDR treatment programme and five-day EMDR treatment programme were well tolerated

without exacerbation of symptoms, even in patients with severe PTSD and comorbidity. In our study we focus on unresolved traumatic memories and flash forwards related to the diagnosis and illness of their child, and we do not suspect a highly vulnerable research population with severe psychopathology. Important to note is that parents will be called by the researcher within three months after the two-day EMDR treatment to ask if they need more psychosocial support. Moreover, parents will be told at the last treatment day that they can call at any time if they need more psychological support before the end of the study. Parents may benefit from the intervention as EMDR is recognized as an effective first line treatment for reducing posttraumatic stress symptoms and a wide variety of psychological comorbidity. If the two-day EMDR treatment turns out to be effective for parents, future parents of severely ill children may benefit from the treatment and family centred care in the Emma Children*s Hospital could be permanently improved. Moreover, it is known that stress symptoms in parents have a great impact on the well-being of the child, even on very young children or children with a cognitive disability. Therefore treatment is highly relevant for both the psychosocial wellbeing of the parent and the child.

Parents have to fill in online questionnaires at their home that last approximately 35 minutes at a time (three or four time points depending on the allocated arm). The burden of these measurements are considered minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Reporting at least 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 (1 B symptom, 1 C symptom, 2 D symptoms and 2 E symptoms) measured by the PTSD Check List for DSM-5 (PCL-5) or having at least an increased 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 the 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 and/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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-03-2020
Enrollment:	14
Type:	Actual

Ethics review

Approved WMO

Date:	03-01-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	22-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL69719.018.19
Other	NL8496