RELAX: Effect of EMDR for reduction of pain interference in children with sickle cell disease

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The primary objective of this study is to investigate the efficacy of EMDR therapy in reducing pain interference in the life*s of children with SCD. Secondary objectives are to study the efficacy of EMDR in reducing PTSD symptoms, anxiety,...

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

Summary

ID

NL-OMON56978

Source
ToetsingOnline

Brief title
RELAX

Condition

- Haemoglobinopathies

Synonym
Sickle cell disease; Sickle cell anemia

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: For Wis(h)dom Foundation

Intervention

Keyword: EMDR, Pain interference, PTSD, Sickle cell disease

Outcome measures

Primary outcome

Primary outcomes is pain interference in the child*s life, measured with PROMIS Pain Interference questionnaire.

PROMIS Pain Interference (parent-report for children aged 6-7 and pediatric self-report from 7 years on):
We will use the PROMIS Short Form - Pain Interference 8a for measuring Pain interference. The PROMIS Pain Interference questionnaire assess the pain impact on relevant aspects of one*s life. This includes the extent to which pain affects social, cognitive, emotional, physical, and recreational activities. It also incorporates items probing sleep and enjoyment in life. The questionnaire assesses pain interference over the past seven days (recall period). A higher PROMIS T-score represents more pain interference. This scale ranges from 0-100 points. In his dissertation, Luijten reports that the general Dutch pediatric population reports a mean score of 39 points with a standard deviation of 10 points. Therefore, T-scores of 49 and above represent (sub)clinical level of functioning. On previous study from our group (submitted), children with severe SCD phenotype (n= 36) reported a mean score of 52.73 points (SD= 12.72), while the ones with less severe SCD phenotype (n= 54) reported a mean score of 47.35 points (SD= 13.82).

Secondary outcome

• Severity of PTSD symptoms during/after intervention:

PTSD symptoms score reported via the Child and Adolescent Trauma Screen (CATS) questionnaire (parent-report for children aged 6-7 and pediatric self-report from 7 years on):

The Child and Adolescent Trauma Screen (CATS) questionnaire is a screening instrument based on the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria for PTSD. It is a measure of potentially traumatic events and of PTSS. These questionnaires are composed of 15 items measuring traumatic events, 20 items measuring DSM-5 PTSD symptoms, and 5 items measuring psychosocial functioning, and is administered in approximately 15 minutes. The 4-point symptom response scales indicate the reported frequency/severity of each symptom. For the children aged 6 years, using the Caregiver-report, the possible score range is 0 - 48, and the recommended cut-off point indicative of (sub)clinically relevant level of symptoms is of 12 points or more. For children aged 7 years and older, using the Self-report version, the possible score range is 0 - 60, and the cut-off point is of 15 points or more.

• Anxiety of participants (parent-report for children aged 6-7 and pediatric self-report from 7 years on):

General anxiety score reported via PROMIS Anxiety questionnaire:

PROMIS Anxiety questionnaires assess the fear (fearfulness, panic), anxious,

misery (worry, dread), hyperarousal (tension, nervousness, restlessness), and somatic symptoms related to arousal (racing heart, dizziness). They assess anxiety over the past seven days (recall period). The PROMIS T-scores are calculated per version. A higher PROMIS T-score represents more anxiety.

• Depressive symptoms of participants (parent-report for children aged 6-7 and pediatric self-report from 7 years on):
PROMIS Depressive Symptoms questionnaires assess negative mood (sadness, guilt), views of self (self-criticism, worthlessness), and social cognition (loneliness, interpersonal alienation), as well as decreased positive affect and engagement (loss of interest, meaning, and purpose). Somatic symptoms (changes in appetite, sleeping patterns) are not included, which eliminates consideration of these item*s confounding effects when assessing children with comorbid physical conditions. The questionnaires are universal rather than disease-specific, making scores easily comparable to the general population. They assess depressive symptoms over the past seven days (recall period). The PROMIS T-scores are calculated per version. A higher PROMIS T-score represents more depressive symptoms.

• Physical complaints (parent-report for children aged 6-7 and pediatric self-report from 7 years on):
These questionnaires assess activities of physical mobility such as getting out of bed or a chair to activities such as running. They assess mobility over the past seven days (recall period). The PROMIS T-scores are calculated per

version. A higher PROMIS T-score represents more mobility.

• Pain severity and intensity, pain medication and school absence:

At 3 measurement moments (T0, T1, T1.1. and T2) participants, should complete a diary and report for each day of the week if they had pain and rate the severity of the pain on a numeric rating scale (NRS), and any pain medication used and if they went to school.

Pain severity will also be investigated before and after each EMDR session using the same measurement tool, and will be registered by the therapist as part of the session report.

• Feasibility of EMDR intervention:

At T1i/T1.1c (2 weeks after the last EMDR session), the EMDR treatment feasibility will be evaluated via a semi-structured interview performed by the researcher with the participants.

Study description

Background summary

Children with sickle cell disease (SCD) suffer from vaso-occlusive episodes (VOE), extremely painful acute episodes that may occur frequently (on average 3x/year), unexpectedly, and usually last several days. The severity of pain of these VOE may require hospitalization for the administration of morphine. Traumatic experiences during hospitalization may lead to the development of (subclinical) posttraumatic stress disorder (PTSD). A first-choice treatment for PTSD is Eye Movement Desensitization and Reprocessing (EMDR) therapy. Studies demonstrated the efficacy of EMDR in decreasing PTSD symptoms in children and adolescents, EMDR therapy is also reported to be effective in treating acute and chronic pain symptoms in adults. EMDR, however, has not been

studied for children and for SCD populations with the aim of reduction in pain interference.

Study objective

The primary objective of this study is to investigate the efficacy of EMDR therapy in reducing pain interference in the life*s of children with SCD. Secondary objectives are to study the efficacy of EMDR in reducing PTSD symptoms, anxiety, depressive symptoms, physical complaints (low mobility), frequency and severity of pain, use of pain medication, and number of days absent from school. Themes of pain and trauma related memories and feasibility of EMDR therapy for this population will also be explored.

Study design

In this single-center randomized controlled trial (RCT) patients (age 6-18 years) with SCD and clinical relevant scores on PROMIS pain interference will be randomized into an intervention group and wait-list control group. Measurements will be done for the complete study population at inclusion (T0). In the intervention group measurements will be done 2 weeks (T1i) and 3 months (T2i) after the end of EMDR sessions. Eight weeks after inclusion (T1c) will be performed for participants in the wait-list control group just before they receive EMDR treatment, and they are asked to complete measurements, 2 weeks (T1.1c) and 3 months after the end of EMDR sessions (T2c).

Intervention

After the intake session (week 1), including case conceptualization and treatment plan, a maximum of 6 weekly EMDR sessions with a duration of 1 hour per session will be offered. The wait-list control group will wait 9 weeks before starting EMDR therapy.

Study burden and risks

This research may benefit the subjects (therapeutic), with the potential to reduce pain interference and PTSD symptoms. Participants will spend a maximum total of 7.5 hours for EMDR therapy (including intake). At home, per measurement moment, the maximum estimated time to answer to all questionnaires online is approximate 15 minutes. Participation in the study is associated with negligible risks for children and their 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 children*s hospital. As with any form of psychotherapy, there may be a mild temporary increase in distress, caused by processing of the information discussed with the therapist. However EMDR is proven to be very effective in decreasing stress levels immediately and after the session. The therapist will be available for

the patients in case they need support in between EMDR sessions. Moreover, participants/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. In addition, 3 months after completion of the EMDR participants will be called by the research team to ask if they need more psychosocial support. Participating in this study may be beneficial in different ways. Firstly, in case the treatment is proven to be effective in reducing pain interference, it will contribute to clinical care as a non-invasive and non-pharmacological treatment of SCD. Secondly, when efficacy of EMDR for SCD pain interference is demonstrated, this intervention may be further studied for children with SCD suffering from pain world-wide and children with other types of pain, may also benefit from the use of EMDR therapy.

Contacts

Public
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

Children (2-11 years)

Inclusion criteria

• Medical diagnosis of SCD;
• Age between 6 and 18 years old;
• Elevated pain interference scores:
Reporting above the clinical cut-off t-score of 49 on PROMIS Pain Interference (parent-proxy version for children from 6-7 years and self-report version for children from 8 years).
• Having sufficient knowledge of the Dutch or English languages to complete the assessments;

Exclusion criteria

• Undergone succesful stem cell transplantation;
• Pregnant adolescents;
• Current unsafety that is likely to interfere with psychological therapy for example ongoing domestic violence;
• Major interfering acute medical or psychiatric condition, such as psychosis, substance dependence, current severe self-harm or high risk for suicide requiring immediate treatment;
• Receiving psychological (trauma) treatment by another therapist at the same time;
• IQ estimated to be < 80 based on information contained in the medical history or information from educational services/school.

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:	Recruiting
Start date (anticipated):	20-09-2024
Enrollment:	40
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	29-08-2024
Application type:	First submission
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	NL86274.018.24