

# Effectiveness of EMDR for adolescents with Major Depressive Disorder

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This study aims to investigate the effectiveness of EMDR (n=32) in comparison to a waiting list in (n=32) adolescents (12-18 years) with a primary diagnosis of MDD (DSM-5; American Psychiatric Association, 2013). It is hypothesized that the...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Completed
<b>Health condition type</b>	Mood disorders and disturbances NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON54319

### Source

ToetsingOnline

### Brief title

EMDR for adolescent MDD

### Condition

- Mood disorders and disturbances NEC

### Synonym

depressive disorder, mood disorder

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Stichting Rivierduinen

**Source(s) of monetary or material Support:** GGZ Rivierduinen

## Intervention

**Keyword:** adolescents, EMDR, Major Depressive Disorder

## Outcome measures

### Primary outcome

Hypothesis 1: The application of EMDR therapy is associated with a significant decrease in severity of depressive symptoms (CDI-2) and decrease of percentage of patients meeting DSM-5 criteria for MDD (K-SADS-PL-5) compared to the waiting list.

Primary study parameters:

- Childrens Depression Inventory-2 (CDI-2)
- Schedule for Affective Disorders and Schizophrenia for School Age Children

Present and Lifetime Version (K-SADS-5-PL)

### Secondary outcome

Hypothesis 2: The application of EMDR therapy is associated with a significant decrease in severity of co-morbid symptoms (CATS, SCARED, SDQ) compared to the waiting list.

Study parameters:

- Child and Adolescent Trauma Screen (CATS)
- Screen for Child Anxiety Related Emotional Disorders (SCARED)

Hypothesis 3: Treatment effect is predicted by baseline posttraumatic stress symptoms severity (CATS), family functioning (FAD) and having experienced emotional abuse or neglect (CTQ).

Study parameters:

- Child and Adolescent Trauma Screen (CATS)
- Family Functioning Device (FAD)
- Childhood Trauma Questionnaire (CTQ)

## Study description

### Background summary

Major depressive disorder (MDD) is one of the most common psychiatric disorders of childhood and adolescence (Mullen, 2018). It has been estimated that 14 to 25% of adolescents experience at least one episode of a depressive disorder before entering adulthood (Ryan, 2005). MDD is a leading cause of disability in terms of burden of disease and poor functioning (Smith, 2014; Stikkelbroek, Bodden, Dekovi\* & van Baar, 2013). Furthermore, MDD with adolescent onset has been found to be associated with a range of physical health problems and other mental health disorders in adult life (Thapar, Collishaw, Pine & Thapar, 2012; Weersing, Jeffreys, Do, Schwartz & Bolano, 2017) as well as with social problems, legal problems, and elevated suicide risk (Stikkelbroek et al., 2013). Current treatments show limited effectiveness and high drop-out and relapse rates. For example, the mean effect size of Cognitive behavioural therapy (CBT), which is recommended as evidence-based psychosocial intervention for MDD in the NICE guideline (2019), was only 0.29 in a meta-analysis of CBT for adolescent MDD (Weisz et al., 2017). In a Dutch multicentre study carried out in specialized mental health institutions (Stikkelbroek, 2016) CBT was not found to be more effective than treatment as usual (TAU). In fact, CBT performed worse on both drop-out and the number of adverse events during treatment than TAU. Hence, the development of innovative strategies for treatment of MDD, especially during adolescence, is of paramount importance in order to enhance the number of adolescents that profit of treatment.

A developing body of research highlights the role of family relationships and interactions as being particularly relevant to the onset and maintenance of MDD

in adolescents (Feeny et al., 2009; Schwartz et al., 2012; Stein et al., 2000). Family functioning is rated as more dysfunctional in families with a depressed adolescent (e.g. Tamplin, Goodyer & Herbert, 1998) compared to families without mental disorders. Family functioning predicts onset of adolescent MDD (e.g. Wang, Tian, Guo, & Huebner, 2020) and possibly treatment outcome (e.g. Feeny et al 2009, Rengasamy et al., 2013).

Also, the role of distressing experiences that relate to the development and maintenance of MDD has been recognized for decades (Monroe, Slavich and Georgiades, 2014, Mandelli, Petrelli & Serretti, 2015). More specifically, it was found that traumatic interpersonal experiences, like humiliation and entrapment (Kendler et al., 2003), and different forms of childhood abuse, primarily emotional abuse and emotional neglect (Hovens et al., 2010, Mandelli et al., 2015) are related to MDD. Moreover, having a history of childhood trauma predicts poor efficacy of treatment (Barbe, Bridge, Birmaher, Kolko & Brent, 2004; Lewis et al. 2010; Nanni, Uher & Danese, 2012), which highlights the importance of identifying trauma histories and adding trauma focused interventions when treating depressed adolescents (Lewis, 2010).

Eye movement desensitization and reprocessing (EMDR) therapy (Shapiro, 2017) appears to be a promising treatment for MDD in adolescents (Paauw, De Roos, Tummers, De Jongh & Dingemans, 2019). According to the recent treatment guidelines EMDR therapy (Shapiro, 2017) is one of the recommended treatments for posttraumatic stress disorder (PTSD; ISTSS Guidelines Committee, 2018; World Health Organization, 2013). It has been found to be capable of processing memories of distressing events (Shapiro, 2017). In the past five years several studies have been conducted demonstrating preliminary evidence for the efficacy of EMDR therapy in the treatment of MDD in adults. Promising results were obtained from studies investigating EMDR therapy as an adjunct therapy to CBT (Hoffman et al., 2014), to pharmacological treatment (Ostacoli et al., 2018, Minelli et al., 2019) and to inpatient treatment (Hase et al., 2015; 2018). Three studies, investigating the efficacy of EMDR as a stand-alone treatment, demonstrated significant reductions of depressive symptoms (Gauhar, 2016), even for patients with long-term depression (Wood, Ricketts & Parry, 2018) and treatment-resistant depression (Minelli et al., 2019). Treatment of MDD also resulted in significant decreases of trauma symptoms (Gauhar, 2016) and anxiety symptoms (Minelli et al., 2019), improved social functioning (Minelli et al., 2019) and quality of life (Gauhar, 2016). In addition to the abovementioned randomized controlled trials (RCTs), various case studies and pilot studies were also conducted (see Wood & Ricketts (2013) and Carletto et al. (2017). However, the listed studies were all focused on adult patients. A first larger effectiveness study with adolescents (apart from a case series by Bae, Kim & Park; 2008) was recently carried out by our group, where we included 32 adolescents with MDD as a primary diagnosis in an outpatient youth mental healthcare institution (Paauw, De Roos, Tummers, De Jongh & Dingemans, 2019). After 6 EMDR sessions, 60.9% of the adolescents who finished treatment, no longer met DSM-IV criteria of MDD and the severity of comorbid anxiety, posttraumatic stress symptoms and somatic complaints were significantly

reduced. At follow-up measurement three months after treatment, these results were maintained. Since these results were very promising more high quality studies are needed (e.g. with a randomized controlled design, a larger number of participants and a longer follow-up period).

## **Study objective**

This study aims to investigate the effectiveness of EMDR (n=32) in comparison to a waiting list in (n=32) adolescents (12-18 years) with a primary diagnosis of MDD (DSM-5; American Psychiatric Association, 2013). It is hypothesized that the application of EMDR therapy is associated with a significant decrease in severity of depressive symptoms and decrease of percentage of patients meeting DSM-5 criteria for MDD compared to the waiting list. Furthermore, we hypothesize that treatment will be associated with a significant decrease in severity of co-morbid symptoms (i.e., post-traumatic stress symptoms, anxiety, somatic and overall social-emotional problems) compared to waiting list. In addition, we will examine whether baseline posttraumatic stress symptoms severity, family functioning and having experienced emotional abuse or neglect significantly predicts post-treatment outcome.

## **Study design**

In this study patients will be randomly assigned to one of two conditions: (a) EMDR treatment or (b) waiting list condition.

Randomisation will be done (using SPSS function \*random numbers\*) by an independent researcher. Assessments (see figure 1) are scheduled pre-treatment (T0), post-treatment (T1), at 3-months (T2) and at 6-months (T3) follow-up.

Assessment will be done by a team of independent assessors (i.e., trained clinicians and master level students) who are blind for the condition.

Participants in the waiting list condition are offered EMDR treatment after T1, subsequently they are also assessed post-treatment and at 3- and 6-months follow-up (see Figure 1).

The primary outcome variables are depressive symptoms (as measured by the CDI) and the presence or absence of a MDD diagnosis, based on the Kiddie-SADS Interview (K-SADS-PL-5; Kaufman et al., 2016). Secondary outcomes variables are post-traumatic stress symptoms, anxiety, somatic symptoms and overall social-emotional problems.

Because perceptual differences on symptoms and family functioning between adolescents with MDD and their parents (c.f. Chen et al., 2017) exist, questionnaires will be administered to both adolescents and parents.

## **Intervention**

The Dutch version of the standard EMDR protocol with age-specific adaptations for children and adolescents (De Roos, Beer, De Jongh & Ten Broeke, 2020) will be used. This procedure includes eight phases: history taking, preparation,

assessment, desensitization, installation, body scan, closure and re-evaluation (Shapiro, 2017). Treatment consists of a maximum of six weekly 60-minute individual treatment sessions. When all target memories from the case conceptualisation can be retrieved without emotional disturbance (i.e. SUD related to the memory is reduced to zero) in less than six session, this will be classified as early completion of treatment.

Memories are placed in a hierarchy based on the Subjective Units of Disturbance (SUD), and are treated subsequently from high to low SUD. Each session will be followed by a 15-minute meeting with the adolescent and one or both parents. The content of this meeting is discussed beforehand with the adolescent and comprises any one of the following elements: (1) an outline of the content of the session (2) parents\* view on the course of symptoms in the week before the session and (3) the need and possibilities for emotional support of the adolescent after the session.

Therapists have at least completed both Basic and Advanced EMDR training. All sessions will be videotaped and all therapists participate in monthly two-hour supervisions by a certified EMDR Europe Child and Adolescent Consultant (CdR). Additional supervision by email or telephone is provided on request.

## **Study burden and risks**

Participation in the study is not associated with obvious risks. The burden of participation in the study is small and temporary. Baseline assessment (T0) takes up to two hours to complete; time investment for follow-up assessments (T1-T3) is 1-1.5 hours.

All participants will be offered active treatment, either directly after inclusion, or after 6 weeks waiting list condition.

For participants in both active and waiting list condition a patient safety plan will routinely be made as part of the assessment phase. For participants in the waiting list condition a therapist is available in case of crisis or sudden worsening of symptoms; a record will be made of such contacts. During treatment phase, the therapist and multidisciplinary team, and also the 24-hour crisis team, are available in the same way as during care-as-usual.

If depressive symptoms remain after EMDR treatment, additional treatment interventions can be applied.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adolescents (12-15 years)  
Adolescents (16-17 years)

### **Inclusion criteria**

Inclusion criteria:

- (a) Age 12-18 years
- (b) Major Depressive Disorder (MDD) as primary diagnosis (DSM-5)
- (c) identified memories of at least one distressing or traumatic event related to the depressive symptomatology

### **Exclusion criteria**

- (a) suicidal attempt or serious non-suicidal self-injury requiring hospitalization in the past month
- (b) substance dependence
- (c) IQ estimated to be  $\leq 80$  based on information from the referral letter or diagnostic phase
- (d) insufficient Dutch language skills

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

**Primary purpose:** Treatment

### Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	24-12-2020
Enrollment:	64
Type:	Actual

## Ethics review

Approved WMO	
Date:	03-12-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	28-01-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO	
Date:	05-05-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)



## 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	NL74425.058.20