EMDR with traumatized adolescents with a major depressive disorder

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The aim of this study is to investigate the effectiveness of EMDR with traumatized adolescents (12-18 years) with major depressive disorder.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON43859

Source
ToetsingOnline

Brief title
EMDR for depressive adolescents

Condition

- Mood disorders and disturbances NEC

Synonym
depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Rivierduinen
Source(s) of monetary or material Support: GGZ Rivierduinen

Intervention

Keyword: adolescents, depressive disorder, EMDR, trauma

Outcome measures

Primary outcome

The main (primary) study parameter is the effect of the EMDR treatment on post-traumatic stress symptoms (ADIS-C, UCLA) and depressive symptoms (ADIS-C, CDI 2).

Secondary outcome

Secondary parameters are the effect of the EMDR treatment on comorbid anxiety (SCARED), socio-emotional problems (SDQ) and physical symptoms (CSI). Associations between the level of depressive symptoms and the degree of vividness and emotionality of memory (Questionnaire of Memory Characteristics, item 1 and 5) and the degree of post-traumatic cognitions (CPTCI) are also considered secondary parameters.

Study description

Background summary

Major depressive disorder (DSM-IV (American Psychiatric Association, 2000) or DSM-5 (American Psychiatric Association, 2013), is among psychiatric disorders with highest prevalence during adolescence (12-18 year) (Shirk, Deprince, Crisostomo & Labus, 2014). The prevalance of depression in Dutch adolescents is approximately 3% (Steering Committee on Multidisciplinary Guideline Development in Mental Health Care, 2009).
According to the DSM-IV-TR a Major Depressive Disorder is defined as a depressed mood, during at least two weeks. These changes are characterized by an irritable mood and / or loss of interest and pleasure and. of clinical characteristics such as changes in eating and / or sleeping patterns, agitation or inhibition, feelings of worthlessness, suicidal thoughts and / or suicide attempts. Al these symptoms cause clinically significant impairment in social, work, school and other important areas of functioning (APA, 2000). In the newer 5th version of the DSM (APA, 2013) these criteria have hardly been adapted. A depressive disorder often first emerges during adolescence (Shrik et al., 2014) and its emergence has evident effect on adolescent development. Functioning in

various areas of life is affected. This could include the social functioning, functioning in school but also family-life (Compton et al., 2004; Harrington, Campbell, Shoebridge & Whittaker, 1998 Steering Committee on Multidisciplinary Guideline Development in Mental Health Care, 2009; Weisz, McCarthy & Valeri, 2006). A major depressive disorder often requires a (psychotherapeutic) therapy, also because a depression associated with increased risk for other psychiatric problems such as PTSD, anxiety and somatoform disorders (Weisz, McCarthy & Valeri, 2006). The impact of a depressive disorder is even more evident from longitudinal studies concerning the development of a depressive disorder, showing that depressed individuals have a great opportunity to continue to relapse again in new depressive episodes; within five years 70% will have a new depression (Steering Committee on Multidisciplinary Guideline Development in Mental Health Care, 2009).

The Dutch national guidelines recommend Cognitive behavioral therapy (CBT) as one of the first choice treatments (Steering Committee on Multidisciplinary Guideline Development in Mental Health Care, 2009). CBT treatment involves several components, including cognitive restructuring of negative thoughts, relaxation skills, and increase problem-solving skills (Van Rooijen-Mutsaers, 2013). Although the effectiveness of CBT with depression in adolescence has been demonstrated in a number of mata-analyses (Compton et al., 2004; Harrington et al, 1998, Weisz et al., 2006.), more recent studies show that the effectiveness of CBT treatment might be more limited than previously thought in the introduction of these therapies (Johnsen & Friborg, 2015). Also the long-term effects of treatment are often not maintained (Klein et al., 2007; Watanabe, Hunot, Omori, Churchill & Furukawa, 2007). The improvement of the effect of treatment of depressive disorders in adolescents is therefore necessary. Lewis et al. (2010) found that CBT treatment for depression was less effective for adolescents had a history of trauma. The suggestion of Lewis et al. (2010) to offer the subgroup of depressed adolescents with traumatic experiences a trauma focused treatment could well be an important approach to improve the treatment of depressive disorders in adolescents. An important recent addition to the CBT model for depression (Beck, 1979), where the assumption is that depressive symptoms are caused distortions in cognitive processes, is the role of traumatic events in the onset and maintenance of depressive symptoms (Beck & Bredemeier, 2016). These traumatic events are negative events that have to do with close interpersonal relationships and the acceptance by the peer group important for the development of a sense of identity.

Monroe, Slavich and Georgiades (2014) argue that many, if not most, depressive episodes are preceded by traumatic or negative life experiences. In a meta-analysis (N = 25 studies) of Risch et al. (2009) the risk for the development of a depressive disorder was found in have significantly related to negative life events, but not to e.g. genetic factors. Not only onset, but also maintenance of depressive disorders, was found to be influenced by unprocessed memories of traumatic events (Kendler, Hettema, Butera, Gardner & Prescott (2003). Within the category of traumatic experiences mainly events with an interpersonal aspect are involved, with loss (such as death, divorce, or

material things), humiliation and social exclusion as central themes. The symptoms resulting from such events are very similar to those of post-traumatic stress disorder, including flashbacks and avoidance of memories (Patel, Brewin, Wheatley, Wells, Fiser & Myers, 2007). Spinhoven, Penninx, van Hemert, de Rooij and Elzinga (2014) suggest, because of the high comorbidity between PTSD and depressive disorders, that there might be a shared vulnerability and advise in cases of depressive problems always to screen for the presence of PTSD.
The described relationship between traumatic experiences and the emergence of depression suggests that the use of an evidence-based trauma treatment such as Eye Movement Desensitization and Reprocessing (EMDR) could be an important element in the treatment of major depressive disorder (Hoffmann et al., 2016). The assumption is that when the unprocessed memories of traumatic events are effectively treated, this can result in a reduction of depressive symptoms (Wood & Ricketts, 2013). EMDR is known worldwide as an effective psychotherapeutic treatment for PTSD and is recommended in both international guidelines (eg. WHO, 2013) as the Dutch multidisciplinary directive (National Steering Committee on Multidisciplinary Guideline Development in Mental Health Care, 2003) as first choice treatment for both adults and children and adolescents (Rodenburg, Benjamin, Rose, Meijer & Stams, 2009). In EMDR traumatic memories are the central focus (Logie, 2014; Shapiro, 2001). Most empirical support for the active mechanism of EMDR has been found for the so-called working memory theory. The working memory has a limited capacity (Baddeley, 2012). Remembering a traumatic event involves intense liveliness and emotions and takes the capacity of the memory for the most part. If there should be a distracting task at the same time there is less capacity available for the traumatic memory (Baddeley, 2012). There seems to be competition within the working memory, resulting in less space for the intense memory, reducing the emotional charge and the liveliness of the traumatic memory (Hornsveld et al., 2010). This results in a disappearance of the dysfunctional meaning of the traumatic memory. De Jongh and colleagues (2013) have shown that this process applies to both negative memories related to PTSD, and negative memories associated with other mental disorders, such as depressive disorders.
There are many recent studies on the effectiveness of EMDR in adult trauma patients with depressive disorders. A total of 17 studies is discussed in a literature review from 2013 (Wood & Ricketts). Among these studies, mostly case studies of varying quality, are also two Randomized Clinical Trials (RCTs) (Hogan, 2001; Song & Wang, 2007). In the study (N = 30) of Hogan (2001), the effectiveness of EMDR was compared with CBT, while Song and Wang (2007) compared EMDR plus medication (sertraline) with only medication (total: N = 64). In both studies depressive symptoms declined significantly in the EMDR condition, and improvement was comparable with CBT and medication, respectively. Song and Wang (2007) note that the EMDR treatment resulted in faster improvement, was more safe and resulted in better treatment compliance. Recently an RCT from Pakistan (Gauhar & Wajid, 2016) (N = 26) was published in which 6-8 sessions EMDR was proven more effective than a waiting list. Very large effect sizes were found, with regard to the reduction of trauma-related and depressive symptoms and improvement of quality of life. Remarkably a

significant change in the level of cognitions relevant to depression was also found, although cognitions are not explicitly focused on with EMDR treatment (unlike in CBT).
In addition to these initial pilot studies have now been initiated large-scale studies into the effectiveness of EMDR with traumatized patients with depressive symptoms. There is a British study going on under the name Sheffield EMDR Depression Investigation (SEDI). In addition, there started a large European research project: The European Depression and EMDR Network (EDEN). Currently, in six European countries studies into the effectiveness of EMDR in depressive disorders are conducted (comparing EMDR treatment with treatment as usual, medication and CBT; trial registered under number ISRCTN09958202; www.ISRCTN.com). The EDEN network has published to studies up to now. Hofmann et. al (2014) studied the effect of EMDR as an addition to regular CBT treatment in 42 ambulatory patients. They found that a significantly higher percentage (90%) of the condition CBT plus EMDR (m = 44.5 + 6.9 sessions resp.) no longer met the criteria for a depressive disorder, compared to the condition CBT alone (m = 47.1 sessions) (38%). In a second publication of the EDEN group (Hase et al, 2015) EMDR was added to the regular clinical treatment program (duration of treatment on average 40 days program including psychoeducation, individual psychotherapy, group psychotherapy and sports). After an average of 5.6 EMDR sessions, patients in the standard treatment + EMDR (N = 16) reported less depressive symptoms (BDI), and general psychological distress (SCL-90) compared to patients who had only received treatment as usual. In 68% of patients in the standard treatment + EMDR condition depression was in remission after treatment (lack of data on remission in the other condition).
To date, a case study (Bae, Kim & Park, 2008) and a controlled case study (Tang, Yang Yen and Liu, 2008) were published specifically testing the effectiveness of EMDR with depressed adolescents. Bae et al. (2008) report on two adolescents in which after treatment with only EMDR (one 3 and the other seven sessions) focused on traumatic experiences (loss of a parent and separation from the parental figure) a significant decrease in depressive symptoms was found. The results were maintained at follow-up after 3-5 months. A larger study was conducted by Tang et al. (2015). They studied a group of 83 Taiwanese adolescents (12-15 years), who were diagnosed with either PTSD, major depressive disorder, a moderate to high risk of suicide (MINI-KID score * 9), or a combination of these problems after experiencing a typhoon. The adolescents were divided into an EMDR condition (n = 41, including 21 with major depressive disorder) and a treatment as usual (TAU) condition (n = 42, including 19 with major depressive disorder). The EMDR condition (4 sessions) was more effective than TAU (psychoeducation) in reducing both depression and anxiety symptoms. In addition, there was both conditions no drop-out and there were no adverse events or side effects.
In summary, it is evident from scientific research that traumatic experiences can play a role in the onset and persistence of depressive disorders. This insight has already been integrated into the underlying theoretical model of CBT by Beck (Beck and Brede Meier, 2016). In clinical

practice, traumatized patients with a depressive disorder are already often treatment with traumafocused treatment. The results of the current studies on the added value of EMDR, as evidence-based trauma treatment, in the treatment of depression are promising.
The aim of this study is to investigate the effectiveness of EMDR with traumatized adolescents (12-18 years) with major depressive disorder. This study also serves to examine whether a reduction of depressive symptoms is predicted by changes in characteristics of the memory (emotionality and vividness of the memory), and / or trauma-related cognitions; to thereby get a clearer understanding about the mechanism of change in treatment.

Study objective

The aim of this study is to investigate the effectiveness of EMDR with traumatized adolescents (12-18 years) with major depressive disorder.

Study design

This study is a randomized controlled trial with two conditions: EMDR versus a waiting list (WL). The study has four measurement points: a baseline (T0) at the start, then after having completed 6 weeks of treatment (T1) and subsequent follow-up measurements after 3 months (T2) and 6 months (T3). In addition, at each treatment session, the severity of the depressive symptoms (CDI-2) is assessed. At session 1, 2, 3 and 6, the vividness and emotionality of the -in the beginning- most stressful depression-related traumatic memory are assessed. Randomization will occur after the baseline (T0). The EMDR treatment condition comprises six weekly individual treatment contacts of 60 minutes, followed by a brief discussion with parents of 15 minutes. The waiting list condition also covers a period of six weeks.

Randomization will be performed by an independent assessor using SPSS (SPSS function "to produce random numbers"). Randomization will be done in blocks of four participants, which will be stratified according to treatment site. This number is based on the estimate that about four adolescents per month can be recruited to participate in the study. In addition, there was a practical consideration, it is assumed that by using this design EMDR treatments can be distributed evenly over time and available practitioners.
The participants in the waiting list condition will be on the waiting list for a period of 6 weeks. The participants in the waiting list condition will undergo an additional measurement of the end of the waiting list condition, before they too offered the EMDR treatment. This measurement is actually the baseline for this group. Then follow the measurement points in accordance with the other condition (T1 after completion of the EMDR treatment, T2 3 months after closing, T3 6 months after closing).

Intervention

EMDR treatment

An assessment of symptoms and depression-related traumatic events is made during the intake phase, which are the building blocks for the case conceptualization which is made by the practitioner.

The participants in the EMDR treatment condition will on a weekly basis have a weekly 60 min. treatment session. The EMDR treatment will be carried out according to the protocol of Shapiro (2001) combined with the age-specific adjustments (the Rose, Bear, de Jongh and ten Broeke, 2015; Greenwald, 1999; Tinker & Wilson, 1999). By default, six sessions will be offered. The EMDR treatment procedure includes eight components namely intake and assessment, preparation, assessment, desensitization, installation, body scan, positive shutdown and re-evaluation (Bear & The Rose, 2012, Shapiro, 2001). Prior to treatment, the practitioner explains the EMDR procedure and a selection of the most stressful memories that are assumed relevant for the depression is carried out. Next, the therapist asks the adolescent to focus on the memory and the memory-related negative/dysfunctional cognition (NC), emotions, subjective unit of disturbance (SUD) and location of the tension in the body are assessed (focusing). Then the therapist provides a distracting task, preferably eye movements, and asks the adolescent to name associations after 30 seconds. Any association with the memory is followed by a new series of eye movements. Regularly the degree of emotional disturbance (SUD) is checked on a 10-point Likert scale. This process will be repeated until the SUD is 0 (desensitization). Then, the memory will be associated with the functional cognition. The participant will be asked the credibility of the positive cognition on the Validity of Cognition Scale (VoC), a 7-point Likert scale. New sets of the distracting task are offered until the adolescent perceives the positive cognition as completely true (VoC = 7; installation). Finally, the therapist will check if the original target image no longer evokes bodily sensations (body scan) and will lead the adolescent to a positive conclusion and re-evaluation of the memory.

In this study the practitioners will fill in a session form after each session, recording target memories, negative cognitions (NC), positive cognitions (PC), subjective units of distress (SUD), scores, validity of cognition (VoC) scores and a description of the process.

Parents / guardians are informed after each treatment session on the progress of the session. This happens in a short (15 minutes per session) face-to-face contact between clinician, adolescent and parents, the content of which is determined in consultation with the adolescent. If high levels of depressive symptoms remain at the end of the EMDR treatment, additional treatment interventions will be discussed with both the adolescent and parents / guardians, and the multidisciplinary treatment team.

Treatment fidelity

EMDR treatments will be performed by GZ Psychologists, Psychotherapists and Clinical Psychologists employed at TOPGGZ PsychoTtrauma Center of Rivierduinen Children and Youth. They are experienced therapists who have attended both the

basic and advanced training EMDR. Through session forms and video recordings it is documented to what extent the treatment protocol is followed. During the study all therapists will take part in monthly supervision sessions, in which video recordings of each case will be shown.
In addition, the case conceptualization for each case will be approved by the supervisor before starting treatment. The supervisor is available by e-mail for intermediate questions for all practitioners.
The treatment fidelity will be assessed by independent evaluators using video recordings.

Early completion
Treatment can be completed at an early stage (<6 sessions) if all selected events from the case conceptualization have no emotional charge (SUD = 0) for the participant and a participant obtaines a CDI score under 16.

Study burden and risks

Participation in the study is not associated with obvious risks. In the treatment condition there is a weekly contact between the practitioner both the adolescent and one of the parents / guardians.
In case of exacerbation of symptoms, both during the treatment process and during any waiting period, regular mental health care facilities like telephone consultation with the practitioner and the 24-hour crisis service are available. Feasibility and desirability of continued participation in the study in these cases will be decided for each individual case.
If high levels of depressive symptoms remain at the end of the EMDR treatment, additional treatment interventions will be discussed with both the adolescent and parents / guardians, and the multidisciplinary treatment team.

Contacts

Public
Stichting Rivierduinen

Sandifortdreef 19
Leiden 2333ZZ
NL
Scientific
Stichting Rivierduinen

Sandifortdreef 19
Leiden 2333ZZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. A mild to moderate depressive disorder according to the criteria of the Multidisciplinaire Richtlijn Depressie bij Jeugd (2009), i.e. 5-8 symtoms according to DSM IV TR, with no severe suicical or psychotic symptoms, interference of the disorders on max. 3 out of 4 life domains (school, social situations, leisure and home/familiy) and a GAF > 45. ;2. Depressive symptoms are related to unprocessed memories of at least one traumatic experience.;3. Age between 12 and 18 years;4. Willingness to participate in the study

Exclusion criteria

1.In case of a long lasting major depressive disorder (conform DSM IV TR criteria), with seriously suicidal behavior and/ or psychotic symptoms and malfunctioning at school, at home and in social situations. ;2. Limited intellectual abilities (IQ < 80) ;3. Insufficient Dutch language skills

Study design

Design

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

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Date:	19-01-2017
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (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	NL55376.058.15