Effectiveness of Eye Movement Desensitization and Reprocessing on Post Traumatic Stress Disorder in persons with mild intellectual disability and psychosis: A multiple baseline study

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The main purpose of this study is to find out whether EMDR is a safe and effective treatment to reduce the symptoms of PTSD in people with mild intellectual disability and borderline intellectual functioning. In addition, it is expected to reduce...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders congenital
Study type	Interventional

Summary

ID

NL-OMON44576

Source
ToetsingOnline

Brief title
Effectiveness of EMDR on PTSD in persons with mild ID and psychosis.

Condition

- Neurological disorders congenital
- Schizophrenia and other psychotic disorders

Synonym
ptsd, trauma

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Oost Brabant (Rosmalen)
Source(s) of monetary or material Support: GGZ Oost Brabant;subsidie moet nog aangevraagd worden + VEN (vereniging EMDR Nederland: subsidie moet nog aangevraagd worden.

Intervention

Keyword: EMDR-PTSD-ID-Psychosis

Outcome measures

Primary outcome

PTSD symptoms

The Adapted Anxiety Disorder Interview Schedule-Adults, PTSD section (ADIS-C-PTSD, LVB-Adult version, unpublished) (Mevissen et al., 2014), is used to measure type and severity of PTSD symptoms in adults with mild ID and borderline IF. Mevissen et al. (2014) developed the Adapted ADIS-C -PTSD for the assessment of PTSD in children and adolescents with mild to borderline IF. A recent study showed good interrater reliability, content and convergent validity (Mevissen et al., in press). Next to the child version, the ADIS-PTSD-LVB-Adult version Interview was developed. At this moment a study on its psychometric characteristics is in progress.

The first part of the ADIS-PTSD-LVB-Adult version consists of 29 questions addressing different types of traumatic events. The response format for each question is *yes*, *no* or *otherwise*. When participant responds to the question about one of the traumatic events in the affirmative, the participant is asked three more questions: (1) *what happened?*; (2) *how did you react to that*; (3) *how old were you when it happened?*. To help the participant to

keep in mind the events when symptoms are asked, all events the participants are exposed to, are visualized on a time line. Next, the participant is asked which event actually is the worst to think about. The second part of the interview consists of 40 questions about PTSD symptoms and several questions addressing atypical symptoms. For these questions, the response format is *yes*, *no* or *otherwise. The participant is then asked to rate his or her subjective level of daily life impairment. To this end a thermometer card is used.

During the selection process the entire interview will be conducted by an EMDR therapist, trained in administering the interview. To monitor the weekly changes in PTSD symptoms only the second part of the interview will be used. The monitoring of the weekly changes will be carried out by a research assistant.

Secondary outcome

Psychotic symptoms

Psychotic symptoms will be weekly monitored by means of the Psychotic Symptom Rating Scale Interview (PSYRATS) (Haddock, 1994), in Dutch translation (Valmaggia, 1998). The interview uses the Auditory Hallucination Rating Scale (AHRS; 11 questions, total score ranges from 0-55). The AHRS assesses the frequency, duration, location, loudness, causal attribution of daily life caused by hearing voices. The Delusion Rating Scale (DRS; 6 questions, total score ranges from 0-30) and assesses the extent and duration of preoccupation with the delusion, the credibility of the delusion, the extent and severity of discomfort and suffering, and the disruption of daily life caused by the

delusions. All PSYRATS items are scored from 0 (not) to 5 (continuously).
Results of a study by Haddock and his colleagues (1999) showed an adequate internal reliability, largely good test-retest reliability and logical inter-correlations between subscales of the PSYRATS interrater reliability (AHRS alphas .78-100; DRS .88-.99) and validity were found to be good to excellent.
Although the PSYRATS (sub-scale AHRS and sub-scale DRS) are used in studies for non-disabled patients, there are indications that it is also useful in people with mild ID and borderline IF. Hatton and his colleagues (2005) found that the PSYRATS, especially the scale for auditory hallucinations, are well-suited to people with ID and psychotic symptoms. In addition, in comparable studies, where participants are included with an IQ of 70, also used the PSYRATS (De Bont, et al., 2013; De Bont et al., 2016, Van den Berg & Van der Gaag; 2012; Van den Berg et al., 2015). This suggests that the PSYRATS can be used reliably in persons with mild ID to borderline IF.
The PSYRATS will be administrated by a research assistant at pre-and post-treatment and follow-up.

General psychopathology and distress
The Brief symptom Inventory (BSI) is a short version of the SCL-90-R to quickly measure psychological symptoms (Derogatis, 1983; 1993) in Dutch translation (De Beurs, 2004). (The BSI has 53 items and contains 9 subscales: requires 8-10 minutes to complete, making it well-suited for repeated administrations over time to evaluate patients* progress. The results of a study by Wieland,

Kapitein, Otter, & Baas (2012) suggest that the BSI is useful in patients with either a mild ID or borderline IF. Internal consistencies ranged from 0.70 to 0.96 and are considered good to adequate. Subscale intercorrelations showed a degree of differentiation between the subscales. Discriminant validity was shown for the subscales depression, anxiety and phobic anxiety. Confirmatory factor analysis showed that the underlying structure of the BSI could be described by the same nine-factor model as reported in previous studies. As a result of the psychometric properties, the study mentioned above supports the use of the BSI as a screener for psychopathology and a general outcome measure in people with a mild ID and borderline IF.
The BSI will be administered by a research assistant at pre- and post-treatment and follow-up.

General psychopathology

The Health of the Nation Outcome Scales (HoNOS) (Wing, Beevor, Curtis, Park, Hadden & Burns, 1998) in Dutch translation (Mulder et al., 2004a) will be used to assess overall mental health and social functioning. The clinician assesses the patient*s situation. The HoNOS has 12 items and contains four subscales; behavioral (problems), (physical & cognitive) impairment, (psychiatric) symptoms, and social (functioning). These items can be scored between zero (*no problem present*) to four (*severe to very severe problem*) (Mulder et al., 2004a). Research results on the HoNOS vary for both test-retest (Orrel, Yard, Handysides, Schapira, 1999) and interrater-reliability (Amin, Singh, Croudace, Jones, Medley & Harrison, 1999; Bebbington, Brugha, Hill, Marsden, Window,

1999; Brook, 2000).. Good training before using the HoNOS is advisable (Amin et al., 1999) and increases interrater-reliability (Brooks, 2000). HoNOS reasonably measures social functioning and general psychopathology and is sensitive to change (Wing, et al., 1998), especially in chronic and more severe psychiatric problems (Amin et al., 1999).

In Dutch research in patients with a mild ID and borderline IF who have severe behavioral and mental health problems the internal consistency of the HoNOS completed by (psychiatric) nurses was 0.74 and 0.48 when completed by psychiatrists/psychologists (Tenneij, Didden, Veltkamp & Koot; 2009).

The HoNOS is part of Routine Outcome Monitoring in GGZ-Oost Brabant and will be administrated by a research assistant at pre- and post-treatment and follow-up.

Study description

Background summary

Persons with mild intellectual disabilities (ID) and borderline intellectual functioning (IF) have 2 to 4 times more chances of developing psychiatric disorders (Dekker, Koot, Van der Ende, & Verhulst, 2002; Neijmeijer, et al., 2013) as ptss (Mevissen & De Jongh , 2010; Didden et al., 2016; Wielland et al., 2014) a psychosis (see eg, Cooper et al., 2007; Welch et al., 2011; Morgan et al., 2008; Zammit et al. 2004). Although PTSD is common in psychosis, few studies have been conducted on effective treatment methods in non-disabled with comorbid PTSD and psychosis. Past or present comorbid psychotic disorder is the highest criterion for exclusion in random clinical PTSD outcomes studies (Bradley, Green, Russ, Dutra, & Westen, 2005; Powers, Halpern, Ferenschak, Gillihan, & Foa, 2010; Ronconi, Shiner, & Watts, 2014; Spinazzola, Blaustein & Van der Kolk, 2005). Research shows that 87% of clinicians see comorbid psychosis as a contraindication for psychotherapeutic intervention, such as long-term exposure (PE) (Becker, Zayfert, & Anderson, 2004). They feared failure or symptom aggravation or the induction of false memories in this vulnerable group (Becker et al., 2004; Van Minnen, Hendriks, & Ollf, 2010, 2010; Read, Hammersley & & Rudegeair, 2007). It is very important to investigate effective treatments for individuals with a mild ID to borderline

IF and comorbid PTSD and psychosis. Since cognitive behavioral therapy mainly includes verbal interventions, homework assignments and exercises outside the sessions, this treatment seems less suitable for this target group. Treatment studies in persons with mild ID and borderline IF are limited (Gilderthorp, 2014; Mevissen & De Jongh, 2010; Mevissen, Lievegoed & De Jongh, 2011; Mevissen et al., 2016; Mevissen, 2016). Jowett and colleagues (2016) conclude from a literature review of 6 case studies that there are sufficient indications that EMDR is a safe intervention for this group of patients in the intellectual and adaptive skills of persons with a mild ID and borderline IF.
Researchers of this current research are not aware of (published) studies on the effectiveness of EMDR on PTSD in persons with mild ID and borderline IF and psychosis. In studies in the general population it appears that EMDR is a safe and effective method and even positively affects psychotic symptoms (see, for example, De Fur, Van Minnen, De Jongh, 2013, De Bont, Van den Berg, Van der Vleugel, & De Roos, 2016; Van den Berg & Van der Gaag, 2012).

Study objective

The main purpose of this study is to find out whether EMDR is a safe and effective treatment to reduce the symptoms of PTSD in people with mild intellectual disability and borderline intellectual functioning.
In addition, it is expected to reduce the severity of symptoms of PTSD in people who have a slight identifier to the F-boundary and psychosis after edder treatment. In addition, it is expected that Amdere will also improve overall performance and reduce mental complaints: hallucinations and hallucinations. (Psi) and General

Study design

The present study uses a multiple baseline across subjects design. When patients are eligible, they will be randomly allocated to different baseline (B) lengths (a-e). The start of the therapy will be randomized over 3-7 weeks of the baseline phase. Studies comparable to the proposed research (See de Bont, et al., 2013, de Bont et al., 2016; Verhagen et al., in preparation) have similar baseline lengths. For each baseline phase, two participants will be randomly assigned. Participants will be weekly assessed with primary measures during baseline (B), treatment (T) and post-treatment (P). Secondary measures in order to measure auditory hallucinations, delusions and general psychopathology will be applied at three time points (t1-t3). That is, before and after treatment and at follow-up (FU), three months after the end of treatment (Table 1).

Table 1 Planning of measurements

Baseline a : t1 BBB TTTTTTTTTTTt2 PPPPPPP t3 FU
Baseline b : t1 BBBB TTTTTTTTTTTt2 PPPPPP t3 FU

Baseline c : t1 BBBBB TTTTTTTTTTTt2 PPPPP t3 FU
Baseline d : t1 BBBBBB TTTTTTTTTTTt2 PPPP t3 FU
Baseline e : t1 BBBBBBB TTTTTTTTTTTt2 PPP t3 FU

t1= baseline B= baseline 3-7 weeks T=treatment 12 weeks, P=post treatment 2-6 weeks, t2= post treatment measurement, t3 FU= follow up after 3 months.

During baseline, each participant will be assessed weekly for a period between 3-7 weeks on the ADIS-C-PTSD-LVB-Adult version (only the second part) and potential/possible adverse events, and once on the AHRS, DRS, BSI and HoNOS (t1). During the treatment phase (12 weeks) participants will be measured weekly on the second part of the ADIS-C-PTSD-LVB-Adult version interview and potential/possible adverse events. Participants will be assessed weekly for 3-7 weeks after the end of treatment on the ADIS-C-PTSD-LVB-Adult version (second part) and potential/ possible adverse events. During this phase (t2) they will also be assessed once on the AHRS, DRS, BSI and HoNOS. Three months after the end of treatment (t3), participants will be assessed on all measures (i.e., ADIS-C-PTSD-LVB-Adult version (second part), AHRS, DRS, BSI and HoNOS.

Intervention

EMDR is an eight-phase protocolized approach intended to resolve the symptoms that can result from disturbing and unprocessed life experiences (Shapiro, 2001). The patient is asked to focus on an image that provides negative emotional reaction. Then the patient is asked to call this disturbing event in mind and focus on the most intrusive still image (called *target*), and the negative thought about oneself (negative cognition), the negative emotion and physical stress that is caused by the target. At the same time the patient is asked to concentrate on a distracting task, preferably following the fingers of the therapist moving from left to right. This is called desensitization and is repeated until the negative charge on the target has become neutral and the (physical) tension has decreased (Shapiro, 2001). Finally, the patient is asked to replace his or here negative cognition with a positive cognition.
At the core of the EMDR method, the working memory taxation plays an important role as an explanation for the treatment effects (Van den Hout & Engelhard, 2011; Ten Broeke, De Jongh, & Oppenheim, 2012). The working memory has a limited capacity and is therefore unable to retain the aversive memory (target) in all its intensity while simultaneously paying attention to another task. As a result, the memory is stored less vividly and emotionally (Engelhard, Van den Hout, & Smeets, 2011; Gunter & Bodner, 2008; Kavanagh, Freese, Andrade, & May, Van den Hout & Engelhard, 2011). Negative cognitions associated with the memory of the traumatic event lose credibility and positive cognitions become more believable (Van den Hout & Engelhard, 2011; De Jongh, Ernst, Marques, Hornsveld, 2013; Ten Broeke et al., 2012). This leads to changes in meaningfulness and consolidation of functional representations (Baddeley, 2012).

The treatment as applied in this study
All participants will receive a maximum of twelve EMDR sessions of ninety minutes. Early completion is allowed. For each participant, a case conceptualization based upon the Two Method Approach (Ten Broeke, et al., 2012) will be made, approved by an accredited supervisor of the Dutch EMDR Association. After target selection, the standard EMDR-protocol in Dutch (De Jongh & Ten Broeke, 2011) adapted from Shapiro*s (1995) work will be used. Meanwhile all participants will continue to receive comparable treatment as usual for psychosis delivered by multidisciplinary teams, with care usually consisting of antipsychotic medication and treatment and/or supportive counseling by psychiatrists, psychologists, nurses and case management.

Study burden and risks

Participants will be interviewed and tested before treatment, after treatment, and at three months follow-up. That is a maximum of 24 times in 24 weeks. The measurements will take approximately 360 minutes, no more than 15 minutes each time. Participants will receive a maximum of twelve therapy sessions of maximally 90 minutes each. A session of 90 minutes is according to the guidelines of the general population. Early completion is allowed.
After the EMDR-sessions some participants might experience a short increase in symptoms, which is a common response to this type of therapy. Major adverse events are not to be expected nor have these been documented in previous similar research with persons with or without mild ID and borderline IF (Gilderthorp, 2014; De Bont, Minnen & De Jongh, 2013; Mevissen, Lievegoed & De Jongh, 2011a; Mevissen, Didden, Korzilius, & De Jongh, Van den Berg et al., 2015). Therapists are experienced in working with persons with mild ID to borderline IF and psychosis and performing EMDR in persons with mild ID and borderline IF and PTSD.

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

Ten participants between 18 and 65 years of age will be recruited for this study. They are mental care patients (i.e. at GGZ Oost Brabant). They receive health care from the specialist department for persons with mild Intellectual disorders to borderline Intellectual functioning and mental disorders (LVB-P circuit).
All participants are diagnosed with a mild ID or borderline IF on the basis of results of an intelligence test (e.g. WAIS II; WAIS IV). Participants have a current psychotic disorder, as assessed by the Mini PAS-ADD (M.i.n.i International Neuropsychiatric interview-Psychiatric Assessment Schedules for Adults with Developmental Disabilities (Prosser, Moss, Costello, Simpson, & Patel, 1997), in Dutch translation (Moss & Van Gennep, 2008), and a current PTSD as assessed by the by the Anxiety Disorder Interview Schedule-Children section PTSD which has been adapted for Adults with mild ID and borderline IF (ADIS-C-PTSD-LVB-Adult version) (Mevissen, Barnhoorn, Didden, & De Jongh, 2014).

Exclusion criteria

Exclusion
-poor language skills (dutch)
-IQ <60
-no full mental competence
-high suicide risk
-severe substance abuse
-change in medication <2months

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2018
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	21-03-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL63533.091.17