The efficacy of Eye Movement Desensitization and Reprocessing on Post Traumatic Stress Disorder symptoms in persons with mild to borderline intellectual disability: A multiple baseline study

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Exploratory studies should be followed by more controlled - in terms of internal validity - studies, as a result of which we may begin to draw more firm conclusions regarding the efficacy of EMDR in persons with mild to bordeline ID who present with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON42628

Source
ToetsingOnline

Brief title
EMDR for PTSD symptoms in persons with mild to bordeline ID

Condition

- Anxiety disorders and symptoms

Synonym
Post traumatic Stress disorder, Trauma

Research involving

Human

Sponsors and support

Primary sponsor: GGZ Oost Brabant (Rosmalen)
Source(s) of monetary or material Support: GGZ Oost Brabant en mogelijk de Vereniging EMDR Nederland (VEN)

Intervention

Keyword: EMDR, Intellectual disablility, PTSD

Outcome measures

Primary outcome

PTSD symptoms

The Adapted Anxiety Disorder Interview Schedule-Adults, PTSD section (ADIS-C-PTSD-LVB-Adult version; unpublished) is used to measure type and severity of PTSD symptoms in adults with mild to bordeline ID. Mevissen et al. (2014) developed the Adapted ADIS-C -PTSD for the assessment of PTSD in children and adolescents with mild to bordeline ID. A recent study showed good interrater reliability, content and convergent validity (Mevissen et al., submitted). 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 (Mevissen et al in press)
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: *what happened?*, *how did you react to that* and *how old were you when it happened?* Events the participants are exposed to

are visualized on a time line, to help the participant to keep in mind the events when symptoms are asked for. 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. The entire interview is conducted by an EMDR therapist, trained in administering the interview to diagnose PTSD. To monitor the weekly changes in PTSD symptoms only the second part of interview will be used. The monitoring of the weekly changes will be carried by a research assistant, trained in administering the interview.

Secondary outcome

Depressive symptoms

Participants* depressive symptoms will be measured with the Becks Depression Inventory-II (BDI-II) (Beck, Steer, Ball, & Ranieri, 1996). The BDI-II consists of 21 items and scores range between zero (symptom not present) and three (symptom clearly present). A higher total score indicates more severe depressive symptoms. External validity and test-retest reliability have shown to be good. Internal consistency is also high (* = .91). Results of studies in persons with mild to borderline ID suggest that the BDI-II can be used in this target group and that the BDI-II is reliable and valid (Lindsay, Skene & Danielle, 2007). The BDI-II will be administrated by a research assistant

during the selection process of the participants, at baseline, posttreatment and follow up.

General psychopathology

The Health of the Nation Outcome Scales (HoNOS) (Wing, Beevor, Curtis, Park, Hadden & Burns, 1998) in Dutch translation (Mulder, Staring, Loos, Buwalda, Kuijpers, Sytema, & Wierdsma, 2004) will be used to assess overall mental health and social functioning. The nurse assesses the participant*s situation with the inpatients or an counselor for the outpatients. The HoNOS has 12 items and contains four subscales: behavioral problems, limitations, symptomatology and social problems. These items can be scored between zero (*no problem present*) and four (*severe to very severe problem*) (Mulder et al., 2004). Research results on the HoNOS vary for both test-retest (Orrel, Yard, Handysides, Schapira, 1999) and interrater reliability (Bebbington, Brugha, Hill, Marsden, Window, 1999; Brooks, 2000). Training before using the HoNOS is advisable (Amin et al., 1999) and increases interrater reliability (Brooks, 2000). The HoNOS 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 with participants with a mild to borderline ID who have severe behavioral and mental health problems the internal consistency of the

HoNOS was .48, when rated by psychiatrist/psychologist, and .74 when rated by psychiatric nurses. Interrater reliability of the HoNOS is fair to good.
Participants with a mild to borderline ID scoring higher on the HONOS showed more emotional and behavioral problems and less adaptive functioning than participants scoring lower on the scale (Matson, Anderson & Bamburg, 2000; Tenneij et al., 2009).
The HoNOS is part of the Routine Outcome Monitoring in GGz Oost Brabant and will be administered by a at baseline, posttreatment 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. The BSI is brief and requires 8-10 minutes to complete, making it well-suited for repeated administrations over time to evaluate patient progress. In a psychometric study of Wieland et al. (2009), a total of 224 psychiatric outpatients participated with either borderline intellectual functioning or mild ID. All participants were new patients of Kristal, Centre for Psychiatry and Intellectual Disability in the Netherlands.
The results suggest that the BSI is useful. Internal consistencies ranged from .70 to .96 and are considered good to adequate. Subscale intercorrelations showed a degree of differentiation between the subscales. Discriminant validity was shown for the sub-scales 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 present study supports the use of the BSI as a screener for psychopathology and a general outcome measure in people with ID. The BSI will be administered by a research assistant, at baseline, posttreatment and follow up.

Study description

Background summary

Persons with mild to borderline ID have been found to be more likely to experience traumatic events - especially sexual en physical abuse - than their nondisabled peers. Due to impairments in their cognitive and adaptive skills, processing life events is supposed to be especially difficult (Focht-New, Barol, Faulkner & Pekala, 2008; Mevissen, Didden & de Jongh, in press; Ryan, 1994; Tsakanikos, Bouras, Costello & Holt, 2007). They seem to be at a greater risk of suffering from the disruptive effects of trauma, including the development of a Post Traumatic Stress Disorder (PTSD; Mevissen & De Jongh, 2010). Accordingly, PTSD is expected to be a common mental health disorder in this population. There is however no evidence regarding the prevalence of PTSD in the ID population. With the few studies that have been conducted rates between 2.5% and 60% are reported (Mevissen & De Jongh, 2010). Professionals working with persons with an ID often lack this awareness and PTSD symptoms could be falsely interpreted as belonging to the ID (diagnostic overshadowing) or misinterpreted as features of other mental disorders (Mevissen & de Jongh, 2010; Mevissen et al., in press; Turk et al., 2005). To make matters more challenging many professionals not working in the health care system for persons with an ID fail to identify persons with a mild to bordeline ID (Neijmeijer et al., 2013). It is generally assumed that relatively many patients have a mild to bordeline ID (Neijmeijer et al., 2013). In the forensic psychiatric field prevalence rates of ID range from 15 to 25% (Emmerik, 2001; RSJ, 2013). As a last example, in the city of Rotterdam 122 patients who receive Assertive Community Treatment were screened for an ID and 68% of patients were found to have an IQ below 85 (Neijmeijer et al., 2013). Failure to recognize an ID and/or a PTSD leads to underdiagnosis and, therefore, undertreatment of individuals with ID. From studies in the general population it is known that if untreated, PTSD is associated with increased physical morbidity, subsequent psychiatric illness, accidental and non-accidental death . It is generally accepted that chronic stress associated with PTSD is related to somatic problems such as ischemic heart disease, asthma, arthritis, cancer and susceptibility to infection (Flannery, 1999). Depression is common in persons with PTSD (Goenjian,Walling, Steinberg,

Najarion & Pynoos, 2006) and there is an increased incidence of alcohol and other substance use (Flannery, 1999). The impact on social, academic and occupational functioning may be considerable (Alisic, Jongmans, van Wessel & Kleber, 2011, Flannery, 1999). Results of a study by Priebe et al. (2009) showed that many years after trauma exposure, patients were still having a PTSD going along with high costs of care and low levels of subjective quality of life.

EMDR Treatment for persons with PTSD and mild to bordeline ID

Trauma Focused CBT and EMDR therapy are the only psychotherapies recommended by the World Health Organization (WHO) for the treatment of PTSD. However, for persons with an ID and PTSD, within the treatment options for psychological trauma, EMDR therapy seem the most suited, particularly considering its non-verbal character and the lack of need to do homework and practice outside the sessions (Mevissen, Didden & de Jongh, in press). EMDR treatment studies in persons with mild to bordeline ID are rare (Gildenthorp, 2014; Mevissen & De Jongh, 2010; Mevissen et al., in press). Gildenthorp (2014) presented a review of studies that evaluated the use of EMDR for persons with ID and PTSD. She found five articles and they all utilized case study designs (i.e., Mevissen et al., 2011a; Mevissen et al., 2011b; Mevissen et al., 2012; Rodenburg et al., 2009; Barol & Seubert, 2010). Results of these studies indicated that EMDR is feasible and promising in the treatment of PTSD for individuals with mild to borderline ID.

Study objective

Exploratory studies should be followed by more controlled - in terms of internal validity - studies, as a result of which we may begin to draw more firm conclusions regarding the efficacy of EMDR in persons with mild to bordeline ID who present with PTSD (Gildenthorp, 2014; Mevissen et al., in press). The present study is a controlled study examining the efficacy of EMDR in the treatment of PTSD symptoms with persons with mild to bordeline ID. Its primary objective is to determine the efficacy of EMDR in the reduction of Post Traumatic Stress Disorder symptoms in this target group. It is hypothesized that the severity of PTSD symptoms will be reduced following EMDR treatment. Furthermore, we hypothesize that EMDR will also lead to an improvement in general functioning and a reduction in psychopathology (e.g., depression).

Primary objective of this study is to determine efficacy of EMDR on Post Traumatic Stress Disorder symptoms in persons with a mild to borderline ID.

Study design

The current study uses a multiple baseline across subjects design, in which participants will be randomly allocated to different baseline (B) lengths (a-e). When patients are eligible, the start of their therapy will be randomized over week 3-7 of the baseline phase. A study comparable to the proposed research (see de Bont, 2013; van der Linde & de Jongh, in preparation) has 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 posttreatment (P). Secondary measures 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.

Intervention

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 work will be used. At the core of the EMDR method is taxing the working memory theory (Engelhard, van den Hout & Smeets, 2011). In the present study, this is operationalized by bilateral stimulation (BLS), either in visual form, the rapid movement of the fingers back and forth across the client field of vision, or in auditory or physical formats, whilst the participant is asked to focus on an image that provides negative emotional reactions. To help foster closure, each session ends on a positive note.

Study burden and risks

EMDR treatment studies in persons with mild to bordeline ID are rare (Gildenthorp, 2014; Mevissen & De Jongh, 2010; Mevissen et al., in press). Gildenthorp (2014) presented a review of studies that evaluated the use of EMDR for persons with ID and PTSD. She found five articles and they all utilized case study designs (i.e., Barol & Seubert, 2010; Mevissen et al., 2011a; Mevissen et al., 2011b; Mevissen et al., 2012; Rodenburg et al., 2009). Results

of these studies indicated that EMDR is feasible and promising in the treatment of PTSD for individuals with mild to borderline ID and no adverse effects were reported in these studies. However, exploratory studies should be followed by more controlled - in terms of internal validity - studies, as a result of which we may begin to draw more firm conclusions regarding the efficacy of EMDR in persons with mild to bordeline ID who present with PTSD (Gildenthorp, 2014; Mevissen et al., in press).
A more general purpose is that we want to contribute to a good treatment provision/guidelines for persons with an ID and PTSD so they get the right treatment. Especially because we know that untreated PTSD (in the general population) is associated with increased physical morbidity, subsequent psychiatric illness, accidental and non-accidental death (APA, 2013).
Participants will be interviewed and tested before treatment, after treatment, and at three months follow-up. For each participant, PTSD symptoms will be measured in the baseline phase, between sessions and in the post treatment phase that is 24 times in 24 weeks. In takes no more than 15 minutes a week. The measurements will be done by an telephone interview in the baseline and posttreatment phase or before the EMDR session so that participants do not have to make an extra appointment. This will take approximately 400 minutes in total. Participants will receive a maximum of twelve therapy sessions of maximally 90 minutes each. A session of 90 minutes is conform the guidelines of the general population.
After EMDR-sessions some participants might experience a short-term 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 research with persons with or without an ID. Therapists are experienced in performing EMDR with persons with a PTSD and a mild to bordeline ID.

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

Recruited for this study will be ten participants who are between 18 and 65 years of age and who are patients of a mental health facility (i.e., GGZ Oost Brabant). They receive health care from the specialist department for persons with mild ID and psychiatric problems (LVB-P circuit). Patients are receiving outpatient care or inpatient care. Those who receive outpatient care, receive care of the GGZ and of an organization specialized in the care for individuals with intellectual disabilities.
All participants are diagnosed with a mild to bordeline ID on the basis of results of an intelligence test (e.g., WAIS-III, WAIS IV) and a questionnaire for adaptive functioning, the Sociale RedZaamheids schaal voor verstandelijk gehandicapten (SRZ-P; Kraijer & Kema, 2004). Participants have a current PTSD, as assessed by the Anxiety Disorder Interview Schedule *Children section PTSD adapted for Adults with MBID (ADIS-C-PTSD-LVB-Adult version).

Exclusion criteria

Exclusion criteria are an IQ below 60, no competence of the Dutch language, severe substance abuse and not having a support system. The support system is this study can be delivered by the clinic were the participant stays, family/friends or care givers from an other organization.
For safety, participants with a BDI-score higher than 35 and a suicide attempt in the past three months, and patients deferring further treatment, are excluded as well. All participants have full mental competence, and people with mental incompetence are excluded. (See figure 1, appendix).
Patients are not excluded based on the severity of other symptoms or problems related to their mental health condition.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2016
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	22-01-2016
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	NL55553.091.15