

# Eye Movement Desensitization (EMD) to reduce posttraumatic stress disorder-related stress reactivity in Indonesian PTSD patients: a study protocol for a randomized controlled trial

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<b>Registration date</b> 19/12/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/07/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Current plain English summary as of 14/01/2020:

### Background and study aims

Posttraumatic stress disorder (PTSD) may develop after exposure to a traumatic event. Eye Movement Desensitization and Reprocessing (EMDR) is an evidence-based psychological treatment for PTSD. It is yet unclear whether eye movements also reduce stress reactivity in PTSD patients.

The aim of this study is to test whether eye movements, as provided during Eye Movement Desensitization (EMD), is more effective in reducing stress reactivity in PTSD patients, as compared to a retrieval-only control condition.

### Who can participate?

Adults aged 18 years and older with posttraumatic stress disorder (PTSD)

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group will receive EMD treatment. Those in the second group will receive a similar therapy but excluding the eye movements. After four to six sessions in each condition, stress reactivity will be measured again (T1) as well as symptoms of PTSD to monitor potential changes occurring during the process of treatment. Next, the post-intervention assessment will be conducted, including stress-reactivity and PTSD symptoms. Finally, at six months, a follow-up assessment is conducted to be able to evaluate the longer-term effectively.

### What are the possible benefits and risks of participating?

There is a direct benefit for participation in this study. The participants will gain treatment to reduce their PTSD symptoms. This treatment will help their traumatic problem. Their participation will help us in better understanding of how effective EMD may be beneficial for people who suffer from the traumatic event. Recalling traumatic memories may lead to

uncomfortable feelings that will most likely quickly pass. However, if participants feel an uncomfortable feeling, there are techniques to reduce and calm their emotions. The therapist will give stabilization techniques until they calm.

Where is the study run from?

The study runs from Vrije Universiteit Amsterdam (Netherlands) and takes place in Yayasan Pulih, a trauma center in Jakarta, the “psychology service Unisba” in Bandung and the “crisis center Unjani” in Cimahi. All of the cities are in Indonesia.

When is the study starting and how long is it expected to run for?

April 2018 to September 2020

Who is funding the study?

BUDI LN\_LPDP (Indonesian Endowment Fund for Education) (Indonesia)

Who is the main contact?

1. Prof.dr.Anja C.Huizink (Scientific)

a.c.huizink@vu.nl

2. Dr. Marit Sijbrandij (Scientific)

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3. Prof. Wilis Srisayekti

wilis@unpad.ac.id

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Previous plain English summary:

Background and study aims

Eye Movement Desensitization and Reprocessing (EMDR) is one of the most effective therapy for Posttraumatic Stress Disorder (PTSD). EMDR is a therapy that uses eye movement to help patient's process distressing memories and beliefs. However, part of the scientific community is skeptical about EMDR, especially whether eye movements or other laterally alternating stimuli play a role in the EMDR effect. It is necessary to provide evidence-based interventions to reduce PTSD-symptoms effectively and efficiently. These treatments are associated with decreases in avoidance, re-experiencing, negative cognitions, and mood-related symptoms. Interventions that not only reduce the PTSD behavioral symptoms but also tackle the underlying psychoneuroendocrine (the relationship of hormones and human behaviour) mechanisms may potentially offer long-term effectiveness. Psychoneuroendocrine mechanism that may play a role in PTSD includes physiological stress reactivity and neuroendocrine stress response. Comprehensive understanding of both behavioral PTSD symptoms and their association with psychophysiological parameters will contribute to the development of indicators of prognosis of treatment outcome and preventive interventions in high-risk groups. The aim of this study is to examine whether regular EMDR treatment is more effective than a similar treatment but without the eye movement components (retrieval only) in terms of reducing PTSD symptoms in PTSD patients. The goal is to investigate whether EMDR results in a more positive change in stress reactivity associated with PTSD symptom reduction as compared to the retrieval only.

Who can participate?

Adults aged 18 and older who attend in the mental health clinic with fulfilling diagnostic criteria for posttraumatic stress disorder (PTSD).

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group will receive the EMDR treatment. Those in the second group will receive a similar therapy but excluding the

eye movements. After four sessions in each condition, stress reactivity will be measured again (T1) as well as symptoms of PTSD to monitor potential changes occurring during the process of treatment. Next, the post-intervention assessment will be conducted, including stress-reactivity and PTSD symptoms. Finally, at six months, a follow-up assessment is conducted to be able to evaluate longer-term effectively.

What are the possible benefits and risks of participating?

There is a direct benefit for participation in this study. The participants will gain treatment to reduce their PTSD symptom. This treatment will help their traumatic problem. Their participating will help us in better understanding how effective EMDR may be beneficial for people who suffer from the traumatic event. Recalling traumatic memories may lead to uncomfortable feelings that will most likely quickly pass. However, if participants feel an uncomfortable feeling, there are techniques to reduce and calm their emotion. The therapist will give stabilization technique until they calm.

Where is the study run from?

The study run from Vrije Universiteit Amsterdam (Netherlands) and takes place in Yayasan Pulih, trauma centre in Jakarta, Indonesia.

When is the study starting and how long is it expected to run for?

February 2017 to October 2019 (updated 21/05/2019, previously: May 2019)

Who is funding the study?

BUDI LN\_LPDP (Indonesian Endowment Fund for Education) (Indonesia)

Who is the main contact?

1. Prof.dr.Anja C.Huizink (Scientific)

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2. Dr. Marit Sijbrandij (Scientific)

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## Contact information

### Type(s)

Scientific

### Contact name

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ID\_01

## Study information

### Scientific Title

Eye Movement Desensitization (EMD) to reduce posttraumatic stress disorder-related stress reactivity: a study protocol for a randomized controlled trial

### Study objectives

Current study hypothesis as of 14/01/2020:

Patients with PTSD receiving the EMD condition will show larger reductions in stress reactivity in response to trauma scripts and stronger improvements in neurocognitive functioning than the retrieval-only control group.

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Previous study hypothesis:

1. Psychophysiological parameters of PTSD participants show more positive alterations in the EMDR condition as compared to the retrieval only condition
2. Psychophysiological parameters of PTSD participants show a more positive change in stress reactivity associated with PTSD symptom reduction in the EMDR condition as compared to the retrieval only condition.

Sub-hypothesis :

- 2.1 Heart Rate level is lower in participants in the EMDR condition
- 2.2 Cortisol Daily output shows a more normal pattern in the EMDR condition

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

The Research Ethics Committee Universitas Padjadjaran Bandung, 26/06/2018, 655/UN6.KEP/EC/2018

### Study design

Interventional randomized controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**Health condition(s) or problem(s) studied**

Posttraumatic stress disorder

**Interventions**

Current interventions as of 14/01/2020:

In this study, the design is a randomised controlled trial (RCT) by blocked randomisation. If a participant meets inclusion criteria a baseline assessment, pre-intervention (T0) is conducted before he or she are randomised and introduced to the corresponding study arm (study arm 1 and 2). Participants are randomised to one of two groups. This study compares the EMDR condition with an exposure condition, which consists of a similar therapy protocol but excluding the eye movements.

The time span between T0 and the first intervention session are kept to about one to two weeks. After four sessions in each condition, stress reactivity is measured again (T1) as well as symptoms of PTSD to monitor potential changes occurring during the process of treatment. Next, post-intervention assessment are conducted (T2), including stress-reactivity, brain activity and PTSD symptoms. Finally, at six months (T3) a follow-up assessment is conducted to be able to evaluate longer-term effectivity. The follow-up assessment are performed in two steps. First, participants are contacted personally and motivated to complete the follow-up instrument. In case participants refuse the telephone interview, they are offered an assessment of the primary outcome only. If participants still refuse, they are asked to provide reasons for their refusal, which is documented.

The endpoints of the study change in neurobiological parameters; Heart rate (HR), Heart Rate Variability (HRV) and Pre-ejection (PEP) responses to trauma-related stimuli. Secondary outcomes of the study are change of cortisol level and reduction in PTSD symptoms based on Clinician-Administered PTSD Scale (CAPS-5), and PCL-5 (PTSD Checklist for DSM-5). CAPS-5 is a structured interview designed to examine the major symptoms of Post-Traumatic Stress Disorder. It consists of item PTSD symptom questions corresponding to DSM-5 diagnosis for PTSD. PCL-5 consists 20 items that assess the 20 DSM 5 symptom of PTSD.

**EMD treatment protocol**

The procedures of EMD intervention will be carried out in line with the standard EMDR protocol (Shapiro & Maxfield, 2002). Since we aimed to evaluate the effects of eye movement during retrieval of a traumatic memory, we decided to omit the installation phase from the original EMDR procedure in both study groups. It has been suggested that the installation phase may be counter-effective, since performing eye movements when retrieving a positive cognition or image (as done in the installation phase), may render that positive image less vivid and positive (van den Hout & Engelhard, 2012). EMD will be given during 4 to a maximum of 6 sessions, and each session lasts 45 -60 minutes. The therapist will provide at least 4 sessions and stop when the Subjective Units Distress (SUDs) scales = 0 or 1 for all target memories. SUDs are measure

the level of distress before and after target memory processing, where 0 is no disturbance or neutral and 10 is the highest disturbance.

EMD consists of the following steps: 1) Client History and treatment planning: obtaining information regarding the clients' clinical condition, including intrusive emotions and physical sensations. 2) Preparation: building a therapeutic bond with the client, the explanation of EMDR process and its effects. 3) Assessment: identification of the target visual image of the traumatic memory and associated negative emotions. The participant describes the intensity of the negative emotions on a 0-10 SUDs scale). 4) Desensitization: clients will be asked to focus on target traumatic events, while focusing their eyes on the therapist's finger that moves from left to right and back in the participant's visual field. The therapist will conduct EM for 24 cycles several times. This phase will end if SUD scores reach 0 or 1. Next, participants will scan their body until any tension disappears. 5) Closure: the session is closed, and the stabilization techniques and relaxation exercises are reviewed. Sessions 2-4 will start with a reevaluation of the patient's progress and SUD scores of target events to guide the choice of continuing with the target traumatic event or choosing a new event.

The EMD treatments will be performed by experienced psychotherapists with at least one year of experience in treating PTSD patients. Eight therapists are planned to be recruited through colleagues from the Clinical Psychologist Association (IPK). Therapists will be weekly supervised by an accredited EMDR supervisor.

#### Retrieval only condition (control)

Control participants will receive the same treatment as the participants in the EMD group, except that during phase 4) Desensitization, no eye movements will be performed during retrieval of the trauma memory.

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#### Previous interventions 14/01/2020:

In this study, the design is a randomised controlled trial (RCT) by blocked randomisation. If a participant meets inclusion criteria a baseline assessment, pre-intervention (T0) is conducted before he or she are randomised and introduced to the corresponding study arm (study arm 1 and 2). Participants are randomised to one of two groups. This study compares the EMDR condition with an exposure condition, which consists of a similar therapy protocol but excluding the eye movements.

The time span between T0 and the first intervention session are kept to about one to two weeks. After four sessions in each condition, stress reactivity is measured again (T1) as well as symptoms of PTSD to monitor potential changes occurring during the process of treatment. Next, post-intervention assessment are conducted (T2), including stress-reactivity, brain activity and PTSD symptoms. Finally, at six months (T3) a follow-up assessment is conducted to be able to evaluate longer-term effectivity. The follow-up assessment are performed in two steps. First, participants are contacted personally and motivated to complete the follow-up instrument. In case participants refuse the telephone interview, they are offered an assessment of the primary outcome only. If participants still refuse, they are asked to provide reasons for their refusal, which is documented.

EMDR therapy is given in six sessions, each session lasts 45-60 minutes. The standard procedure of EMDR are followed: Client history and treatment planning, preparation, assessment, desensitization, installation, body scan, closure, and re-evaluation. In session 1, all procedures steps are conducted and in the others sessions (session 2 to 7), the therapy can be given from the second stage (preparation) and continued to stage 7 (closure) following reevaluation stage, to see the progress of the individual. In the control group, there is no eye movement during exposure of desensitization and installation phases while all the other components of the

treatment protocol are kept the same. This tests whether the addition of Eye Movements is necessary to result in better treatment outcomes on both a behavioral level and on a psychoneuroendocrine level.

The endpoints of the study change in neurobiological parameters; Heart rate (HR), Heart Rate Variability (HRV) and Pre-ejection (PEP) responses to trauma-related stimuli. Secondary outcomes of the study are change of cortisol level and reduction in PTSD symptoms based on Clinician-Administered PTSD Scale (CAPS-5), and PCL-5 (PTSD Checklist for DSM-5). CAPS-5 is a structured interview designed to examine the major symptoms of Post-Traumatic Stress Disorder. It consists of item PTSD symptom questions corresponding to DSM-5 diagnosis for PTSD. PCL-5 consists 20 items that assess the 20 DSM 5 symptom of PTSD.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Current primary outcome measure as of 14/01/2020:

Heart Rate Variability (HRV) measured using the VU AMS device at baseline (T0), during intervention (T1), post-treatment (T2) and six months follow up (T3)

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Previous primary outcome measure:

1. Heart Rate (HR)/Heart Rate Variability (HRV) is measured using the VU AMS device at baseline (T0), during intervention (T1), post-treatment (T2) and six months follow up (T3)
2. Pre-ejection period (PEP) is measured using the VU AMS device at baseline (T1), during intervention (T1), post-treatment (T2) and 6 months follow up (T3)

## **Secondary outcome measures**

Current secondary outcome measures as of 14/01/2020:

At baseline (T0), during intervention (T1), post-treatment (T2) and 6 months follow up (T3):

1. Heart Rate (HR) measured using the VU AMS device
2. Pre-ejection period (PEP) measured using the VU AMS device
3. Diagnosis of DSM-5 Axis I disorder using the SCID-5 questionnaire
4. PTSD symptoms using the PCL-5
5. Experiences of traumatic events using Live Events Checklist (LEC)
6. Anxiety and depression symptoms using The Hopkins Symptoms Checklist-25 (HSCL-25)
7. Perceived feelings and thought of stress during the last month using The Perceived Stress Scale (PSS)
8. Quality of life using the Indonesian version of the World Health Organization Quality of Life (WHOQOL-BREF)
9. Neurocognitive Functioning using the Digit Span subtest of the Indonesian WAIS-IV
10. Encoding, short-term retrieval, and recognition of verbal information using The California Verbal Learning Test (CVLT)
11. Information processing speed, shift of attention, planning, and cognitive flexibility using The Trail Making Test (TMT)

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Previous secondary outcome measures:

1. Cortisol level is measured using salivary samples using The Salimetrics Cortisol Enzyme Immunoassay Kit at baseline (T0), post-treatment (T2) and six months follow up (T3)
2. PTSD symptom score is measured using CAPS (Clinician Administered PTSD Scale) at baseline (T0), post-treatment (T2) and 6 months follow up (T3)

3. PTSD symptom score is measured using PTSD Checklist for DSM-5 at baseline (T0), post-treatment (T2) and six months follow up (T3)

**Overall study start date**

02/02/2017

**Completion date**

30/12/2020

## **Eligibility**

**Key inclusion criteria**

Current inclusion criteria as of 14/01/2020:

1. Diagnostic and Statistical Manual of Mental Disorder, fifth edition (DSM-5) diagnosis of PTSD as diagnosed with the Structured Clinical Interview for DSM-5 disorders (SCID-5)
2. Age of 18 years or older

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**Previous inclusion criteria:**

1. Individuals who were either diagnosed posttraumatic stress disorder (PTSD) by a professional, i.e., by a clinical psychologist and meet DSM-V-TR, the diagnostic rule which requires at least one criteria of A, B, and C and at least two criteria of D and E and with cut off 33 of PCL-5 score
2. Suffering from posttraumatic stress symptoms on a subclinical level with one symptom in each criterion of PTSD symptoms and with cut off 20 of PCL-5 score
3. Minimal age of 18 years

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

We expect to detect a difference between the EMD condition and the exposure condition of a medium effect size (cohen's  $d = 0.04$ ). Based on this assumption, we need a total sample size of  $n=70$

**Total final enrolment**

91

**Key exclusion criteria**

Current inclusion criteria as of 14/01/2020:

1. Current or previous psychotic disorder
2. Current substance use disorder



3. Acute suicidality
4. Current organic disorder i.e. epileptic, brain damage

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Previous exclusion criteria:

1. Individuals with current organic disorders, psychotic disorders, substance abuse, or suicidal ideation will be excluded
2. Individuals that are currently taking any medication for psychological or psychiatric disorders are excluded

**Date of first enrolment**

01/04/2018

**Date of final enrolment**

30/03/2020

## **Locations**

**Countries of recruitment**

Indonesia

**Study participating centre**

**Yayasan Pulih (The Lead Centre)**

Jl Teluk Peleng No,63 RT 5/ RW8

Pasar Minggu Jakarta Selatan

Jakarta

Indonesia

12520

**Study participating centre**

**Universitas Islam Bandung (UNISBA)**

Lab Psikologi Pasca sarjana UNISBA

Jl Purnawarman no 59

Jawa Barat

Indonesia

40117

**Study participating centre**

**Universitas Jenderal Achamad Yani (UNJANI)**

Laboratorium Fakultas Psikologi Unjani

Jl Terusan Jenderal Sudirman

Cimahi

Indonesia

40521

# Sponsor information

## Organisation

BUDI LN\_LPDP (Indonesian Scholarship)

## Sponsor details

A.A Maramis II Building 2nd floor  
Jl Lapangan Banteng Timur no 1  
Jakarta  
Indonesia  
10710

## Sponsor type

Government

## Website

[www.lpdg.kemenkeu.go.id](http://www.lpdg.kemenkeu.go.id)

# Funder(s)

## Funder type

Not defined

## Funder Name

Indonesia Endowment Fund for Education (LPDP)

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

## Intention to publish date

30/07/2021

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Eka Susanty ([e.s.susanty@vu.nl](mailto:e.s.susanty@vu.nl)).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	04/03/2021	05/03/2021	Yes	No
<a href="#">Results article</a>		25/04/2022	16/05/2022	Yes	No
<a href="#">Results article</a>		27/12/2024	30/12/2024	Yes	No
<a href="#">Results article</a>		16/07/2025	28/07/2025	Yes	No