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The effectiveness of eye movement desensitization and reprocessing (EMDR) 2.0 and the Flash technique with post-traumatic stress disorder (PTSD) patients

Submission date
08/11/2022

Recruitment status
Recruiting

Registration date
10/11/2022

Overall study status
Ongoing

Last Edited
12/12/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Eye movement desensitization and reprocessing (EMDR) therapy is an evidence based treatment for patients suffering from a post-traumatic stress dissorder (PTSD). To investigate if EMDR can be delivered more effective and efficient, an adaptation of EMDR has been developed, called EMDR 2.0 therapy. A recent experimental study among participants without a PTSD diagnosis, suggests that EMDR 2.0 can be delivered more efficiently than standard EMDR therapy in reducing the emotionality and vividness of aversive memories. The Flash technique has originally been developed as a titration technique for patients who find the recall of the traumatic memory during EMDR therapy too disturbing. Currently, is has evolved to a stand-alone trauma treatment. Previous research on the Flash technique showed that it was effective in reducing psychiatric symptoms and vividness and emotionality of aversive memories. These previous studies on EMDR 2.0 and the Flash technique show promising results, but a controlled study with patients diagnosed with PTSD is still lacking. The current study is a randomized controlled trial that aims to investigate EMDR 2.0 therapy and the Flash technique among PTSD patients by comparing them to standard EMDR therapy as standard evidence based treatment. The primary aims are to investigate if EMDR 2.0 and the Flash technique are effective in reducing (complex) PTSD symptoms and diagnosis, and to investigate which treatment is most effective. Also, a primary aim is to investigate which treatment is most efficient in reducing subjective disturbance of traumatic memories and in reducing PTSD symptoms. The secondary aims are to investigate the effectiveness in reducing comorbid psychiatric symptoms, to investigate treatmen acceptability, and to investigate moderators of treatment effectiveness.

Who can participate?
Patients aged 18 years and older, with a primary diagnosis of PTSD, an estimated IQ of above 80, and sufficient understanding of the Dutch language.

What does the study involve?
Participants are randomly assigned to one of three treatment arms: EMDR therapy, EMDR 2.0

therapy, or the Flash technique. All treatments start with a 90 minute case conceptualization session, following six weekly 60-minute treatment sessions (EMDR, EMDR 2.0, or Flash). Before, during, and until 12 weeks after treatment, several symptoms and constructs will be measured. Including: PTSD symptoms and diagnosis, complex PTSD symptoms and diagnosis, depressive symptoms, dissociative symptoms, general psychiatric symptoms, experiential avoidance, and treatment acceptability.

What are the possible benefits and risks of participating?
There are no safety risks involved with the treatments. Previous research involving EMDR therapy, EMDR 2.0 therapy, and the Flash technique has not led to negative consequences. In fact, previous clinical studies show less dysregulation in EMDR conditions as opposed to waitlist conditions for example. When compared to regular treatment for PTSD, the additional time investment for the current study mainly consists of filling out the questionnaires. They will be adminstered a total of 12 times and take around 20-30 minutes, which comes down to a maximum total of 6 hours. A potential benefit for participants is that the delivered treatment can reduce their symptoms, although this is not certain. Patients who still meet the diagnostic criteria for PTSD after the study is completed, will be offered regular treatment. If participants are on a waitinglist for regular treatment, they will keep their place on the waitinglist if they still show symptoms after the course of the study.

Where is the study run from?
The study is run from the Altrecht Academic Anxiety Center in Utrecht, the Netherlands.

When is the study starting and how long is it expected to run for?
April 2021 to October 2026

Who is funding the study?
Altrecht Academic Anxiety Center (the Netherlands)
EMDR Research Foundation (USA)
Vereniging EMDR Nederland (Dutch EMDR association)

Who is the main contact?
Valentijn Alting van Geusau
v.alting-van-geusau@altrecht.nl

Contact information

Type(s)
Principal investigator

Contact name
Dr Suzy Matthijssen

ORCID ID
https://orcid.org/0000-0002-5537-112X

Contact details
Nieuwe Houtenseweg 12
Utrecht
Netherlands
3512 SH

+31 (0)30 2308790
s.matthijssen@altrecht.nl

Type(s)
Public

Contact name
Mr Valentijn Alting van Geusau

Contact details
Nieuwe Houtenseweg 12
Utrecht
Netherlands
3512 SH
+31 (0)30 2308790
v.alting-van-geusau@altrecht.nl

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NL79163.041.22

Study information

Scientific Title
The effectiveness of EMDR vs. EMDR 2.0 vs. Flash technique in the treatment of patients diagnosed with PTSD: A randomized controlled trial

Acronym
ENHANCE

Study objectives
We expect eye movement desensitization and reprocessing (EMDR) 2.0 therapy to be more efficient than EMDR therapy in treating traumatic memories and post-traumatic stress disorder (PTSD) symptoms. We do not have prior expectations with regard to the differential effectiveness of EMDR therapy and EMDR 2.0. With regard to the effectiveness and efficiency of the Flash technique compared to EMDR or EMDR 2.0, we do not have any prior expectations as an RCT among PTSD patients has not yet been conducted. We do expect that the Flash technique will be rated as more acceptable by patients than EMDR therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 14/07/2022, Medical Research Ethics Committee (MREC) NedMec (Heidelberglaan 100,3584 CX, Utrecht, the Netherlands; +31 (0)88 7556376; metc@nedmec.nl), ref: NL79163.041.22

Study design
Monocenter interventional parallel group open randomized controlled superiority trial with three treatment arms

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of (complex) PTSD symptoms in patients diagnosed with PTSD.

Interventions
Participants are randomly assigned to one of three treatment conditions using an online tool (sealedenvelope.com). There are two intervention groups and one control group. Participants in one intervention group will receive EMDR 2.0 therapy and participants in the other intervention group will receive the Flash technique. Participants in the control group will receive standard EMDR therapy. All conditions will consist of six weekly sessions, with a duration of 60 minutes. Follow up lasts 12 weeks.

Intervention Type
Behavioural

Primary outcome(s)
1. PTSD symptoms measured with the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) at baseline, post-treatment (4 weeks after the last treatment session) and follow-up (12 weeks after the last treamtent session) and the PTSD symptom Checklist for DSM-5 (PCL-5) at baseline, weekly during treatment phase and bi-weekly after the last treatment session until 12 week follow-up.
2. PTSD diagnosis measured with the CAPS-5 at baseline, post-treatment and follow-up.
3. Complex PTSD symptoms measured with the International Trauma Questionnaire (ITQ) at baseline, post-treatment and follow-up.
4. Complex PTSD diagnosis measured with the ITQ at baseline, post-treatment and follow-up.

Key secondary outcome(s))
1. Depressive symptoms measured with the Beck Depression Inventory-II (BDI-II) at baseline, weekly during the treatment phase and bi-weekly after the last treatment session until 12-week follow-up.
2. Dissociative symptoms measured with the Dissociative Experiences Scale (DES) at baseline, post-treatment and follow-up.
3. General psychiatric symptoms measured with the Brief Symptom Inventory (BSI) at baseline, weekly during the treatment phase and bi-weekly after the last treatment session until 12-week follow-up.
4. Experiential avoidance measured with the Acceptance and Action Questionnaire-II (AAQ-II) at baseline, weekly during the treatment phase and bi-weekly after the last treatment session until 12-week follow-up.

5. Treatment acceptability measured with four questions that measure several facets which could be grouped under treatment acceptability at the second week of treatment and two weeks after the last treatment session.
6. Treatment efficiency measured with intervention time needed to achieve a Subjective Units of Disturbance (SUD) score of 0 and amount of sessions needed to achieve clinically significant change and a cut-off score on the PCL-5. Intervention time and SUD scores will be measured at treatment sessions and the PCL-5 will be measured weekly during the treatment phase.

Completion date
31/10/2026

Eligibility

Key inclusion criteria
1. A primary diagnosis of PTSD, administered with the CAPS-5.
2. A minimum age of 18 years old.
3. An estimated IQ of above 80.
4. Sufficient understanding of the Dutch language.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. The use of benzodiazepines is a contra-indication for treatment and will be tapered as much as possible before participation. Participants are prohibited to use benzodiazepines 24 hours before or after each treatment sessions.
2. The use of drugs during treatment.
3. The use of alcohol is allowed, with the exception of 24 hours before and after a treatment sessions. For the rest of the week, participants are allowed a maximum of 2 units.
4. Acute suicidality
5. Change in medication during the study or six weeks prior to participation, with the exception of tapering benzodiazepines.

Date of first enrolment
17/10/2022

Date of final enrolment
17/10/2026

Locations

Countries of recruitment
Netherlands

Study participating centre
Altrecht Academic Anxiety Center
Nieuwe Houtenseweg 12
Utrecht
Netherlands
3524 SH

Sponsor information

Organisation
Utrecht University

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
EMDR Research Foundation

Funder Name
Vereniging EMDR Nederland (Dutch EMDR Association)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be available upon request from v.alting-van-geusau@altrecht.nl

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		09/11/2023	01/12/2023	Yes	No
Participant information sheet	version 3		10/11/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes