

# Eye movement desensitization and reprocessing (EMDR): efficacy in improving clinical, neuropsychological, and quality of life in women victims of violence

<b>Submission date</b> 19/08/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/11/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/01/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The number of women victims of violence has increased considerably in recent years, causing physical, mental and social damage.

The aims of this study are

- To evaluate the clinical, neuropsychological profile, and quality of life in women victims of violence-based gender.
- To Analyze the differences that exist between applied psychotherapy and its effects, considering sociodemographic factors.
- To determine the effectiveness of EMDR compared to NET in reducing clinical symptoms, increasing quality of life, and improving cognitive performance.

### Who can participate?

Women between 18 and 50 years of age who have a history of being exposed to physical, psychological and sexual violence, who are also domiciled in the communities of Cayambe and Pedro Moncayo- Ecuador

### What does the study involve?

Two treatment groups will be randomly assigned. The first group (n=60) will receive psychotherapeutic treatment with the EMDR Eye Movement Desensitization and Reprocessing Model, the second group will receive an alternative therapy based on NET narrative exposure therapy. The main purpose is to test the efficacy of the two psychotherapeutic treatments. To test the efficacy of the interventions, pre-posttests of a broad neuropsychological and clinical battery will be applied.

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

The benefits for the women will be to obtain a significant improvement in their mental health, which will allow them to empower themselves, make adequate decisions and abandon the cycle of violence.

The study does not contemplate any risk, since no psychoactive drugs or any instrument that could be harmful will be used. The intervention is purely psychological, and we have ensured with protocols that assess the possible risks, before subjecting the participant to treatment, in this case, it is controlled under exclusion criteria. Finally, the participant may withdraw at any time during the process.

Where is the study run from?

The study was planned in the communities of Cayambe and Pedro Moncayo-Ecuador, with the support of the Tabacundo Type C Health Center, and the medical offices of local flower growers.

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

March 2019 to December 2023

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Alexandra Yakeline Meneses Meneses, jaquellinne@hotmail.es

## Contact information

### Type(s)

Principal investigator

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## Study information

**Scientific Title**

Eye movement desensitization and reprocessing (EMDR): efficacy in improving clinical, neuropsychological, and quality of life in women victims of violence

**Study objectives**

Eye movement desensitization and reprocessing (EMDR)-based psychotherapeutic treatment is more effective compared to NET, for improving the mental health and quality of life of women exposed to violence.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

approved 23/06/2020, Comité de Ética de Investigación en Seres Humanos de la Universidad UTE (CEISH UTE) (Av. Occidental y Mariana de Jesús, Quito, 170525, Ecuador; +593995093288; camilomolinab@usal.es), ref: OF. No. 040-CEISH-jcm

**Study design**

Open randomized experimental study

**Primary study design**

Interventional

**Study type(s)**

Diagnostic, Quality of life, Treatment, Efficacy

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

Women exposed to gender-based violence who show symptoms of anxiety, depression and post-traumatic stress, in addition to low performance in cognitive functioning, or that limits performance in daily life

**Interventions**

A total of 120 women exposed to gender-based violence participated; the women were identified and invited to participate in the study through professionals from the public health network of the Tabacundo Health Center in Ecuador. The participants were randomly divided into two treatment groups.

All selected women were informed of the characteristics and procedures of the study and of the voluntary nature of their participation, and they signed an informed consent form. Women who agreed to participate in the study were administered the Spanish version of the National Adult Reading Test (NART) 46-47 to rule out intellectual disability, and those who met the inclusion criteria underwent the pretest, which consisted of a complete battery to evaluate the clinical profile, cognitive functions, and quality of life of the participants.

Subsequently, the women were assigned to the corresponding therapy groups:

Group A – 60 women who received EMDR therapy

Group B – 60 women who received NET

The treatment plan is made up of 10 sessions, lasting 60 minutes each. After the treatment, the post-test evaluation will be applied. The duration time is estimated at 3 years.

Dropouts that occurred during the treatment phase were considered in the analysis. Following the protocols for the treatment plan designed for each group and the recommendations of the ethics committee, two specialized therapists were assigned to a random list of participants based on the specialty of the therapist, EMDR or NET. Ten personalized therapeutic sessions were scheduled, each with a duration of 60 minutes.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Measurements are made with the pretest (beginning of treatment, includes 10 sessions) and post-test (after 6 months) at the end of treatment:

Neuropsychological functioning was measured using the following tests:

1. The Rey Auditory Verbal Learning Test RAV LT.
2. Coding - subtest WAIS IV.
3. Test D2. measures selective and sustained attention.
4. Trail Making Test, part A (TMT-A) and part B (TMT-B).
5. Stroop Test. An instrument that assesses complex attention.
6. Phonological Verbal Fluency Test PVFT.
7. Semantic Verbal Fluency Test SVFT. Assesses the ability to retrieve stored semantic information.

### **Key secondary outcome(s)**

Measurements are made with the pretest (beginning of treatment, includes 10 sessions) and post-test (after 6 months) at the end of treatment:

1. Gender violence - Questionnaire on violence
2. Anxiety and depression are measured using the Hospital Anxiety and Depression Scale HADS scale
3. Posttraumatic Stress Disorder is measured using the Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5)
4. Quality of Life is measured using GENCAT Scale

### **Completion date**

15/12/2023

## **Eligibility**

### **Key inclusion criteria**

1. Exposed to gender violence (physical, psychological and/or sexual)
2. Between 18 and 50 years of age
3. Signed the informed consent form

### **Participant type(s)**

Patient, Other

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

50 years

**Sex**

Female

**Total final enrolment**

120

**Key exclusion criteria**

1. Intelligence quotient (IQ) lower than 70
2. History of brain damage
3. History of severe neurological or psychiatric illness
4. History of toxic consumption
5. Presence of sensory alterations that impeded the performance of the tests

**Date of first enrolment**

05/05/2019

**Date of final enrolment**

07/07/2020

**Locations****Countries of recruitment**

Ecuador

**Study participating centre**

Tabacundo - Cayambe, Quito - Ecuador

Panamericana Norte

Tabacundo

Ecuador

171004

**Sponsor information****Organisation**

Campus Grupal Foundation

**Funder(s)**

Funder type  
Other

Funder Name  
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan  
<https://data.mendeley.com/datasets/4cbhbv95gk/1>

IPD sharing plan summary  
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		06/12/2024	29/01/2025	Yes	No
<a href="#">Other publications</a>	Clinical Neuropsychological Profile and Quality of Life	25/08/2023	14/12/2023	Yes	No
<a href="#">Other publications</a>	Mental Health and Quality of Life	19/03/2024	29/01/2025	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes