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

Submission date
19/08/2023

Recruitment status
No longer recruiting

Registration date
15/11/2023

Overall study status
Completed

Last Edited
29/01/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

Study website
https://data.mendeley.com/datasets/4cbhbv95gk/1

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Other therapist office, Workplace

Study type(s)
Diagnostic, Quality of life, Treatment, Efficacy

Participant information sheet
https://data.mendeley.com/datasets/4cbhbv95gk/1

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 measure
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.

Secondary outcome measures
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

Overall study start date
03/03/2019

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Female

Target number of participants
170

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
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Sponsor information

Organisation
Campus Grupal Foundation

Sponsor details
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Sponsor type
University/education

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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact refereed journal

Intention to publish date
10/12/2024

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?
Other publications	Clinical Neuropsychological Profile and Quality of Life	25/08/2023	14/12/2023	Yes	No
Other publications	Mental Health and Quality of Life	19/03/2024	29/01/2025	Yes	No
Results article		06/12/2024	29/01/2025	Yes	No