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Effect of an Eye Movement Desensitization and Reprocessing (EMDR)-based therapy on pain and other physical symptoms in patients with fibromyalgia and post-traumatic stress disorder

Submission date
18/01/2022

Recruitment status
No longer recruiting

Registration date
20/01/2022

Overall study status
Completed

Last Edited
21/01/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims:
Fibromyalgia, also called fibromyalgia syndrome (FM), is a long-term condition that causes pain all over the body. Post-traumatic stress disorder (PTSD) is an anxiety disorder caused by very stressful, frightening or distressing events. PTSD often occurs in patients with FM.
Cognitive Behavioral Therapy (CBT) and Eye Movement Desensitization and Reprocessing (EMDR) are the treatments of choice for patients suffering from PTSD.
CBT is a type of therapy that aims to help you manage problems by changing how you think and act.
EMDR is a psychological treatment that's been found to reduce the symptoms of PTSD. It involves recalling the traumatic incident in detail while making eye movements, usually by following the movement of your therapist's finger.

The hypothesis of this study is that specific treatment for PTSD with EMDR based psychotherapy may generate a significant improvement in physical symptoms in patients with FM and PTSD

Who can participate?
Adults older than 18 years with a diagnosis of fibromyalgia and symptoms of PTSD.

What does the study involve?
Participants will be randomized to receive a psychotherapeutic treatment based on EMDR vs standing on the waiting list for 6 months.

What are the possible benefits and risks of participating?
Benefits could be obtained from a treatment that has demonstrated efficacy in treating PTSD. It is a safe therapy with no side effects.

Where is the study run from?
Hospital Universitario Infanta Cristina and Centro asistencial de la Sociedad Española de Medicina Psicosomática (Spain)

When is the study starting and how long is it expected to run for?
July 2017 to September 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr. Juan Torres Macho, juan.torresm@salud.madrid.org

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
HUIC 1/2017

Study information

Scientific Title
Effect of an EMDR-based psychotherapy on physical symptoms in patients with fibromyalgia and post-traumatic stress disorder

Study objectives
Specific treatment for PTSD with EMDR based psychotherapy may generate a significant improvement in physical symptoms in patients with FM and PTSD.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 10/07/2017, Ethics and Research Committee of the Puerta de Hierro University Hospital (ZONA NOROESTE, C/ Joaquín Rodrigo, 2, 28222 Majadahonda / Madrid, Spain; +34 91 191 60 00; secreceic.hpth@salud.madrid.org), ref: n/a

Primary study design
Interventional

Study design
Multicenter randomized clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Fibromyalgia and posttraumatic stress disorder

Interventions
Patients included were randomly assigned to treatment with EMDR through a structured protocol versus remaining on the waiting list for treatment which was offered and applied to this group once the follow-up period (6 months) ended. All the participants continued receiving their usual routine care from their own general practitioners and other healthcare providers. Randomization was performed using a computer-generated randomization list.

Therapeutic intervention:
The therapeutic intervention was carried out on an individual basis using a standardized protocol administered by a team of 20 psychologists and 5 physicians all of them trained in EMDR who were supervised through regular sessions by a senior psychologist with a long experience in EMDR. The EMDR intervention protocol was based on the procedure described by Shapiro (28) but including a modification specifically considered for the treatment of those patients who present high scores in dissociation.

Patients in the treatment arm of the study received 22 individual 90-minute sessions, using this specific EMDR therapy protocol to treat past trauma-related symptoms. The intervention protocol was divided into an initial evaluation and five subsequent steps:

- Initial evaluation: In this phase, the psychotherapist collects information regarding the patient’s biography, including an exhaustive lifeline and the collection of relevant information about the patient's history in order to develop a treatment plan. Some standardized scales and projective techniques are also used to complete the rigorous study of etiology and for the selection of the proper targets which will be treated with EMDR.
This phase lasts for 6 days and the last one is for reading the report written by the psychologist in which the hypothesis about what variables could explain the actual suffering are exposed. It is also the moment for explaining how trauma works causing symptoms and why the intervention includes the use of EMDR. A brief explanation of the technique is also included.
- Step 1. Preparation and widening of the window of tolerance. This is the main difference between Shapiro’s standard protocol and this specific one: the introduction of a phase inside the preparation one to work exclusively with desensitization in order to place the patient into an optimal situation for the intervention to be effective. This is the best way to reverse the effects of dissociation, which are, mainly, re-experimentation phobia and phobia between parts. This way of working also guarantees the necessary dual attention to reprocess and integrate

traumatic experiences. The “lifeline” constructed in the evaluation is employed to work with it while using auditory bilateral stimulation.
Additionally, in this phase, positive resources for emotional regulation are installed. The whole phase is carried out in 4 days.

Step 2. Targeting the traumatic events from the past. There are only four days to work with the past so this phase begins with a session dedicated exclusively to select the targets which will be employed to go with EMDR. This session is crucial for the success of the treatment because it is necessary to find the nuclear events which would explain the major actual suffering and work with them.
Total number of sessions: 5

Step 3. Based on working with the triggers of the present, (four days). The treatment with traumatic experiences must always consider working with past, present, and future in order to ensure good and consistent changes. So, in this phase, the most important triggers related to original trauma are targeted.

Step 4. Based on working with anticipatory anxiety associated with the future. A specific future protocol is used here. Two targets are selected. They represent what the patient considers difficult to face even after all that has been worked during the past months. The cognition “I can do it” is searched and “installed” and as a result, this phase is really empowering and satisfactory. Two sessions are being held here.

Step 5. Closure. The last session is to recapitulate. “Lifeline” is used again to guide the narrative. New explanations and meanings are searched and also new ways to face the requirements of everyday life.

Supervision meetings were on an individual basis and organized at least in five moments during patient's treatment: One after session 3 of the evaluation, another one after finishing it to prepare the report. The third one after the session dedicated to find and measure the targets selected, the fourth during the work with the past, and the last one before the closing session

Intervention Type
Behavioural

Primary outcome(s)
Data were collected at baseline and at the end of treatment or after 6 months of waiting list period.
1. Pain intensity assessed using:
1.1 Visual Analog Scale for pain (VAS pain)
1.2 Brief pain inventory
1.3 Fibromyalgia Impact Questionnaire (FIQ)
2. Fatigue was evaluated using the Multidimensional Fatigue Inventory (MFI-20)
3. Post Traumatic Stress Disorder symptoms were evaluated using the PCL-5

Key secondary outcome(s)
Data were collected at baseline and at the end of treatment or after 6 months of waiting list period.
1. Anxiety was evaluated using the Hamilton Anxiety Scale
2. Depression was evaluated by administering the Hamilton Rating Scale for Depression (HAM-D)

Completion date
01/09/2019

Eligibility

Key inclusion criteria
1. Aged 18 or older
2. Willing to undergo randomization
3. Fulfill modified FM diagnostic criteria from the American College of Rheumatology (2010)
4. Fulfill diagnostic criteria of DSM 5 of PTSD

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
37

Key exclusion criteria
1. Receiving active psychotherapeutic treatment in the last 2 months
2. Started a new pharmacological treatment or a significant dose modification in the last month of a drug already prescribed for FM or PTSD
3. Presence of a significant personality or psychotic disorder or severe depressive syndrome

Date of first enrolment
01/09/2017

Date of final enrolment
15/03/2019

Locations

Countries of recruitment
Spain

Study participating centre

Hospital Universitario Infanta Cristina
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Study participating centre
Centro clinico. Sociedad Española Medicina Psicosomatica
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Sponsor information

Organisation
Hospital Universitario Infanta Cristina

ROR
https://ror.org/05txkk980

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available after anonymization upon request from any other investigator (juan.torresm@salud.madrid.org)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	in Spanish	20/01/2022	No	Yes
Protocol file	in Spanish	20/01/2022	No	No