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The Efficacy of EMDR in Patients With PTSD in Multiple Sclerosis

The recruitment status of this study is unknown because the information has not been verified recently.

Verified December 2012 by San Luigi Gonzaga Hospital.
Recruitment status was Recruiting

Sponsor:
San Luigi Gonzaga Hospital

Collaborator:
Fondazione Italiana Sclerosi Multipla

Information provided by (Responsible Party):
Pier Maria Furlan, San Luigi Gonzaga Hospital

ClinicalTrials.gov Identifier:
NCT01743664

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History of Changes

Purpose

Multiple Sclerosis (MS) can be associated to many psychological symptoms. One of the most relevant is the experience of distress related to the disease, that can lead to the development of Post Traumatic Stress Disorder (PTSD). As far as we know there are no studies on the efficacy of psychological treatments in MS in spite of its relevance for patients' quality of life. Primary aim is to evaluate the efficacy of the treatment with **Eyes Movement Desensitization and Reprocessing(EMDR)** in PTSD secondary to MS. **EMDR** is the elective treatment (together with Cognitive Behavioural Therapy) for PTSD according to international guidelines. The secondary aims are to evaluate the efficacy of **EMDR** on the PTSD-associated symptoms of anxiety and depression and Quality of Life. The study design is a randomized clinical trial. Sixty patients with MS and PTSD will be pre-screened by using the IES-R and the Clinician Administered PTSD Scale. The patients will be randomized in two groups (30 in the experimental group and 30 in the control group).The psychological assessment will be performed in both groups with the same timing and tools: at baseline (T0), after treatment (T1) and 6 months later (T2) by two trained clinical psychologists (independent and blind to treatment) with the CAPS and the administration of self reports: Trauma Antecedent Questionnaire, Chicago Multiscale Depression Inventory, Hospital Anxiety and Depression Scale and Functional Assessment of Multiple Sclerosis. The experimental group will undergo 10 weekly sessions of 60 minutes each with **EMDR** following Shapiro's protocol for traumatic events. The efficacy will be evaluated comparing the results between T0, T1 and T2 and comparing the scores of the experimental and the control groups. Primary outcome measures will be: 1) the proportion of participants at T1 and T2 no longer meeting the Diagnostic and Statistical Manual (DSM IV-TR) diagnostic criteria for PTSD; 2) the reduction of CAPS scores for the four PTSD dimensions from pre-treatment to post-treatment evaluation and follow-up (avoidance, reexperiencing the traumatic event, hyperarousal and numbing). Secondary outcome measures will be: comparison of the scores of CMDI, HADS and FAMS of the two groups at T0, T1 and T2. The statistical procedure applied will be a repeated measures analysis of covariance both on the primary outcome continuous measures and on the secondary ones.

Condition	Intervention	Phase
Posttraumatic Stress Disorders Multiple Sclerosis	Behavioral: **EMDR** Behavioral: Relaxation	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: The Efficacy of **Eye Movement Desensitization and Reprocessing** (**EMDR**) in Patients With Post Traumatic Stress Disorder in Multiple Sclerosis. A Randomized Controlled Trial.

Resource links provided by NLM:

Genetics Home Reference related topics: multiple sclerosis

MedlinePlus related topics: Anxiety Multiple Sclerosis Post-Traumatic Stress Disorder

U.S. FDA Resources

Further study details as provided by San Luigi Gonzaga Hospital:

Primary Outcome Measures:

- Proportion of participants no longer meeting the DSM IV-TR diagnostic criteria for PTSD among patients of the experimental group in comparison with those of the control group after the treatment. [Time Frame: Change from Baseline of number of patients meeting the PTSD DSM IV-TR criteria at 3 months] [Designated as safety issue: No]

Secondary Outcome Measures:

- Reduction in the IES scores after the treatment. [Time Frame: Reduction from Baseline of IES-R score at 3 months] [Designated as safety issue: No]
- Proportion of participants no longer meeting the DSM IV-TR diagnostic criteria for PTSD among patients of the experimental group in comparison with those of the control group at the follow up. [Time Frame: Change from Baseline of number of patients meeting the PTSD DSM IV-TR criteria at 9 months] [Designated as safety issue: No]
- Reduction in the IES scores at the follow-up. [Time Frame: Reduction from Baseline of IES-R score at 9 months] [Designated as safety issue: No]

Other Outcome Measures:

- Reduction of PTS-associated symptoms of anxiety and depression and an improvement in quality of life after the treatment. [Time Frame: Reduction from baseline of PTS-associated symptoms of anxiety and depression and an improvement in quality of life at 3 months.]
  [Designated as safety issue: No]
- Reduction of PTS-associated symptoms of anxiety and depression and an improvement in quality of life at the follow-up. [Time Frame: Reduction from baseline of PTS-associated symptoms of anxiety and depression and an improvement in quality of life at 9 months.] [Designated as safety issue: No]

Estimated Enrollment:	60
Study Start Date:	May 2010
Estimated Study Completion Date:	February 2014
Estimated Primary Completion Date:	March 2013 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Eye Movement Desesitization Reprocessing The **EMDR** protocol follows procedures and phases described by Shapiro (1996). This is a complex treatment that incorporates many different interventions in order to recall trauma-related memories and to subdue them. **EMDR** processing consists of attending to oscillatory stimulation presented in a visual, auditory or tactile modalities, such as moving the finger from side to side across the patient's visual field or presenting an alternating tapping on the hands alternatively. Eye movements are the most commonly used external stimulus, but if the patient has problems with this kind of stimulation, such as headaches or sensomotor deficits, the therapist chooses tapping as an alternative form of oscillatory stimulation with equivalent therapeutic efficacy.	Behavioral: **EMDR** Patients in the experimental group will undergo 10 weekly sessions of 60 minutes each with **EMDR** following Shapiro's protocol for traumatic events
Active Comparator: relaxation Relaxation sessions will include diaphragmatic breathing, progressive muscle relaxation, visualisation, and rapid relaxation.	Behavioral: Relaxation The patients in the control group will undergo 10 weekly relaxation sessions that include diaphragmatic breathing, progressive muscle relaxation, visualization and rapid relaxation.

Show Detailed Description

Eligibility

Ages Eligible for Study:	18 Years to 65 Years (Adult)
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- definite diagnosis of MS (Mc Donald Criteria) evaluated by a neurologist at least six months previously;
- a relapsing-remitting, primary or secondary progressive disease;
- clinically inactive phase of the disease;
- fluent Italian speaker;
- legal capacity to consent to the treatment;

- diagnosis of PTSD assessed with the SCID;
- willingness to suspend all concomitant psychological treatment and suspension of all psychotropic medications at least one month before the treatment or maintenance at baseline level throughout the study.

Exclusion Criteria:

- other serious mental disorders, including bipolar disorders, psychotic symptoms, substance abuse, suicidal tendency or cognitive impairment;
- in corticosteroid treatment during the previous month;
- with other serious medical disorders in addition to MS.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01743664

Contacts

Contact: Luca Ostacoli, M.D. 0039 0119026664 luca.ostacoli@unito.it

Locations

Italy

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Sponsors and Collaborators

San Luigi Gonzaga Hospital

Fondazione Italiana Sclerosi Multipla

Investigators

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More Information

Additional Information:

link to the Italian Association of Multiple Sclerosis and to its Research Foundation EXIT

Publications:

Ostacoli L, Carletto S, Borghi M, Cavallo M, Rocci E, Zuffranieri M, Malucchi S, Bertolotto A, Zennaro A, Furlan PM, Picci RL. Prevalence and significant determinants of post-traumatic stress disorder in a large sample of patients with multiple sclerosis. J Clin Psychol Med Settings. 2013 Jun;20(2):240-6. doi: 10.1007/s10880-012-9323-2.

Chalfant AM, Bryant RA, Fulcher G. Posttraumatic stress disorder following diagnosis of multiple sclerosis. J Trauma Stress. 2004 Oct;17(5):423-8.

Bisson JI, Ehlers A, Matthews R, Pilling S, Richards D, Turner S. Psychological treatments for chronic post-traumatic stress disorder. Systematic review and meta-analysis. Br J Psychiatry. 2007 Feb;190:97-104. Review.

Kangas M, Henry JL, Bryant RA. Posttraumatic stress disorder following cancer. A conceptual and empirical review. Clin Psychol Rev. 2002 May;22(4):499-524. Review.

Tedstone JE, Tarrier N. Posttraumatic stress disorder following medical illness and treatment. Clin Psychol Rev. 2003 May;23(3):409-48. Review.

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Keywords provided by San Luigi Gonzaga Hospital:

Posttraumatic Stress Disorders	Anxiety
Multiple Sclerosis	Depression
Eye Movement Desensitization Reprocessing	Quality of Life
Psychotherapy	

Additional relevant MeSH terms:

Sclerosis	Nervous System Diseases

Multiple Sclerosis
Stress Disorders, Traumatic
Stress Disorders, Post-Traumatic
Pathologic Processes
Demyelinating Autoimmune Diseases, CNS
Autoimmune Diseases of the Nervous System

Demyelinating Diseases
Autoimmune Diseases
Immune System Diseases
Trauma and Stressor Related Disorders
Mental Disorders

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