Purpose

Multiple Sclerosis (MS) can be associated with many psychological symptoms. One of the most relevant is the experience of distress related to the disease, which 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 EMDR (Eye Movement Desensitization and Reprocessing) 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.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
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</thead>
<tbody>
<tr>
<td>Posttraumatic Stress Disorders</td>
<td>Behavioral: EMDR</td>
<td></td>
</tr>
<tr>
<td>Multiple Sclerosis</td>
<td>Behavioral: Relaxation</td>
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</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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</table>
| Experimental: Eye Movement Desensitization Reprocessing | Behavioral: EMDR  
Patiens 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                      | 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. |
| Relaxation sessions will include diaphragmatic breathing, progressive muscle relaxation, visualisation, and rapid relaxation. |                                                           |

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
San Luigi Gonzaga University Hospital Recruiting Orbassano, Torino, Italy, 10043
Principal Investigator: Luca Ostacoli, M.D.

Sponsors and Collaborators
San Luigi Gonzaga Hospital
Fondazione Italiana Sclerosi Multipla

Investigators
Principal Investigator: Pier M Furlan, M.D. San Luigi Gonzaga University Hospital

More Information
Additional Information:
link to the Italian Association of Multiple Sclerosis and to its Research Foundation

Publications:

Responsible Party: Pier Maria Furlan, Head of the Faculty of Medicine and Surgery San Luigi Gonzaga, San Luigi Gonzaga Hospital
ClinicalTrials.gov Identifier: NCT01743664 History of Changes
Other Study ID Numbers: 2009/R/11
Study First Received: November 21, 2012
Last Updated: December 6, 2012
Health Authority: Italy: Ethics Committee

Keywords provided by San Luigi Gonzaga Hospital:
Posttraumatic Stress Disorders
Multiple Sclerosis
Eye Movement Desensitization Reprocessing
Psychotherapy

Additional relevant MeSH terms:
Sclerosis Nervous System Diseases
<table>
<thead>
<tr>
<th>Multiple Sclerosis</th>
<th>Demyelinating Diseases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stress Disorders, Traumatic</td>
<td>Autoimmune Diseases</td>
</tr>
<tr>
<td>Stress Disorders, Post-Traumatic</td>
<td>Immune System Diseases</td>
</tr>
<tr>
<td>Pathologic Processes</td>
<td>Trauma and Stressor Related Disorders</td>
</tr>
<tr>
<td>Demyelinating Autoimmune Diseases, CNS</td>
<td>Mental Disorders</td>
</tr>
<tr>
<td>Autoimmune Diseases of the Nervous System</td>
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</tbody>
</table>

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