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Trial record **7 of 19** for: EMDR

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EMDR vs Supportive Therapy in Relapse Prevention in Traumatized Bipolar Patients

This study is not yet open for participant recruitment. (see Contacts and Locations)

Verified August 2016 by FIDMAG Germanes Hospitalàries

Sponsor:
FIDMAG Germanes Hospitalàries

Collaborators:
Hospital Clinic of Barcelona
Hospital del Mar
Hospital Universitari de Bellvitge
Instituto de Salud Carlos III
Centro de Investigación Biomédica en Red de Salud Mental

Information provided by (Responsible Party):
Benedikt Amann, FIDMAG Germanes Hospitalàries

ClinicalTrials.gov Identifier:
NCT02634372

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History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

The purpose of this study is to determine whether **EMDR** (vs supportive therapy) is effective in relapse prevention over an observational period of 2 years in bipolar patients with a history of traumatic events.

Condition	Intervention
Bipolar Disorder	Behavioral: **EMDR** therapy Behavioral: Supportive Therapy

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

Official Title: Single-blind, Randomized Controlled Comparison of **EMDR** Versus Supportive Therapy in Affective Relapse Prevention in Bipolar Patients With a History of Trauma

Resource links provided by NLM:

MedlinePlus related topics: Bipolar Disorder

U.S. FDA Resources

Further study details as provided by FIDMAG Germanes Hospitalàries:

Primary Outcome Measures:

- Number of depressive, hypomanic, manic or mixed episodes [Time Frame: Change of relapses from baseline to visits at 6, 12 and 24 months] [Designated as safety issue: Yes]

  Affective relapses are defined as: Depressive relapse: score>18 in the BDRS, and a score>3 in the CGI-BP-M, depressive subscale. Hypomanic relapse: a YMRS score between 7 and 20, and a score of 3 or 4 in the CGI-BP-M, the manic subscale. Manic relapse: a YMRS score of >20, and the CGI-BP-M, the manic subscale, score>4. Mixed relapse: a BDRS score>10 in the mixed subscale (max. 15), and a score >4 in the CGI-BP-M, depressive and manic subscales.

Secondary Outcome Measures:

- Depressive symptoms [Time Frame: Change from baseline in depressive symptoms at 3, 6, 12 and 24 months] [Designated as safety issue: Yes]
  To measure changes in depressive symptoms we will use the BDRS, and the CGI-BP-M, the depressive subscale.
- (Hypo)manic symptoms [Time Frame: Change from baseline in (hypo)manic symptoms at 3, 6, 12 and 24 months] [Designated as safety issue: Yes]
  To measure changes in (hypo)manic symptoms we will use the YMRS and the CGI-BP-M, the manic subscale.
- Mixed symptoms [Time Frame: Change from baseline in mixed symptoms at 3, 6, 12 and 24 months] [Designated as safety issue: Yes]
  To measure changes in mixed symptoms we will use the YMRS, the BDRS (mixed subscale) and the CGI-BP-M, the depressive and manic subscale.
- Trauma associated symptoms [Time Frame: Change from baseline in trauma symptoms at 3, 6, 12 and 24 months] [Designated as safety issue: Yes]
  To measure changes in trauma associated symptoms, the CAPS, IES, TLEQ and DEQ will be used.
- Functioning [Time Frame: Change from baseline in functioning at 3, 6, 12 and 24 months] [Designated as safety issue: No]
  To measure changes in functioning the FAST will be used.
- Cognitive impairment [Time Frame: Change from baseline in cognition at 3, 6, 12 and 24 months] [Designated as safety issue: No]
  To measure changes in cognition the SCIP will be used.
- Social cognition and emotional intelligence [Time Frame: Change from baseline in cognition at 3, 6, 12 and 24 months]
  [Designated as safety issue: No]
  To measure changes in social cognition and emotional intelligence the MSCEIT will be used.

Estimated Enrollment: 82
Study Start Date: March 2016
Estimated Study Completion Date: March 2020
Estimated Primary Completion Date: March 2018 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: **EMDR** Therapy **EMDR**: 20 individual sessions 60 minutes each for 6 months	Behavioral: **EMDR** therapy **EMDR**: We designed a specific **EMDR** Bipolar Protocol which consists of a detailed interview with respect to traumatic events, the treatment of those with the **EMDR** standard protocol, and five new specific bipolar adapted **EMDR** protocols focusing on adherence, insight, de-idealisation of manic symptoms, prodromal symptoms and moodstabilization.
Active Comparator: Supportive therapy Supportive therapy: 20 individual sessions 60 minutes each for 6 months.	Behavioral: Supportive Therapy Supportive therapy: Therapists adopt a client-centred focus, meaning that whatever problems the patient presents will be dealt with by providing emotional support and general advise. If no specific topic is mentioned by the patient, information about bipolar disorder and medication will be delivered by the therapist without referring to written or any other material.

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:

- Patients fulfill diagnosis of bipolar I or II disorder, following DSM-IV-RT criteria
- Outpatients
- History of 2 to 6 affective episodes in previous year
- Patients are included in the study 1) in euthymia, defined as Bipolar Depression Rating Scale (BDRS) <8 and Young Mania Rating Scale (YMRS) <8 or 2) with subsyndromal symptoms, defined as BDRS ≥8 and <14 and/or YMRS ≥8 and <12
- Patients suffered at least from one traumatic event, evaluated by the Distressing Event Scale, Traumatic Life Events Questionnaire, Impact of Event Scale and Subjects Units of Distress.

Exclusion Criteria:

- Neurological disease
- Currently in a manic phase (YMRS>18), mixed phase (BDRS≥10 in mixed subscale of BDRS, max.: 15) or depressive phase (BDRS >18)
- Acute suicidal plans
- Substance Use Disorder within last 3 months (except of nicotine abuse/dependency)
- Trauma focused therapy within last 12 months.

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: NCT02634372

Contacts

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Locations

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Hospital Universitari de Bellvitge

Instituto de Salud Carlos III

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Investigators

Principal Investigator: Benedikt L Amann, MD FIDMAG Research Foundation

More Information

Publications:

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Bipolar Disorder
Traumatic event
Eye Movement Desensitization Reprocessing
Supportive therapy
Relapse prevention

Additional relevant MeSH terms:

Bipolar Disorder	Mental Disorders
Recurrence	Disease Attributes
Bipolar and Related Disorders	Pathologic Processes

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