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Eye Movement Desensitization and Reprocessing (EMDR) in Non-specific Chronic Back Pain (LOGIN - EMDR)

This study has been completed.

Sponsor:
University Hospital Heidelberg

Information provided by (Responsible Party):
Prof. Dr. Wolfgang Eich, University Hospital Heidelberg

ClinicalTrials.gov Identifier:
NCT01850875

First received: April 23, 2013
Last updated: May 13, 2016
Last verified: May 2016
History of Changes

Purpose

The study explores the feasibility of **Eye-Movement-Desensitization and Reprocessing** (**EMDR**) in non-specific chronic back pain.

Condition	Intervention
Non-specific Chronic Back Pain	Behavioral: **Eye-Movement-Desensitization-Reprocessing**

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

Official Title: Localized and Generalized Musculoskeletal Pain: Psychobiological Mechanisms and Implications for Treatment (LOGIN) - Subgroups Characterized by Psychological Trauma, Mental Comorbidity, and Psychobiological Patterns and Their Specialized Treatment - **Eye Movement Desensitization and Reprocessing** (**EMDR**) in Non-specific Chronic Back Pain

Resource links provided by NLM:

MedlinePlus related topics: Back Pain

U.S. FDA Resources

Further study details as provided by University Hospital Heidelberg:

Primary Outcome Measures:

- Change in pain intensity [Time Frame: Change from Baseline Pain intensity at average 6 months] [Designated as safety issue: No]

  Numerical rating scale 0-10

Other Outcome Measures:

- functional and structural changes in fMRI [Time Frame: Change from Baseline fMRI at average 6 months] [Designated as safety issue: No]
- Change in the pain experience scale - Pain affect [Time Frame: Change from Baseline pain experience scale levels at average 6 months] [Designated as safety issue: No]

  Geisser et al., 1996

- Change in the Hannover functional ability questionnaire (FFbH) - disability [Time Frame: Change from Baseline disabilty levels at average 6 months] [Designated as safety issue: No]

  Kohlmann et al., 1996

- Change in Quantitative sensory testing (QST)profiles [Time Frame: Change from Baseline QST profile at average 6 months] [Designated as safety issue: No]

According to the protocol by Rolke et al. (2006), developed within the Germany Research Network on Neuropathic Pain (DFNS)

- Change in Conditioned Pain Modulation [Time Frame: Change from Baseline conditioned pain modulation activity at average 6 months] [Designated as safety issue: No]

  difference in pressure pain threshold before and after oscillating heat (2 min.)

- Change in Plasma endocannabinoids and lipids [Time Frame: Change from Baseline endocannabinoids and lipids at average 6 months] [Designated as safety issue: No]

  Plasma levels: AEA (ng/ml), 2-AG (ng/ml), AA (ng/ml), PEA (ng/ml), OEA (ng/ml), AEA (pmol/g), 2-AG (pmol/g), AA (nmol/g), PEA (pmol/g), OEA (pmol/g),

- Change in plasma nerve growth factor levels [Time Frame: Change from Baseline NGF levels at average 6 months] [Designated as safety issue: No]

  Plasma levels in (pg/ml)

- Change in pain drawing/ the spatial extent of the pain [Time Frame: Change from Baseline Pain extent at average 6 months] [Designated as safety issue: No]
- Change in West Haven-Yale multidimensional pain inventory scores [Time Frame: Change from Baseline West Haven-Yale multidimensional pain inventory scores at average 6 months] [Designated as safety issue: No]

  Flor et al., 1990

- Change in chronic pain grade [Time Frame: Change from Baseline chronic pain grade at average 6 months] [Designated as safety issue: No]

  von Korff er al., 1992

- Change in Resilience Scale (RS-11) scores [Time Frame: Change from Baseline resilience scores at average 6 months] [Designated as safety issue: No]

  Schumacher et al., 2004

- Change in Hospital Anxiety and Depression Scale scores [Time Frame: Change from Baseline anxiety and depression levels at average 6 months] [Designated as safety issue: No]

  Zigmond & Snaith, 1983

- Change in Health Survey scores [Time Frame: Change from baseline quality of life level at average 6 months] [Designated as safety issue: No]

  SF-12

- Change in somatization scores [Time Frame: Change from Baseline somatization scores at average 6 months] [Designated as safety issue: No]

  SCL-90R

- Change in medication intake [Time Frame: Change from Baseline medication intake at average 6 months] [Designated as safety issue: No]
- Change in dissociation scores [Time Frame: Change from Baseline dissociation at average 6 months] [Designated as safety issue: No]

  DES/FDS-20

- Change in Post Traumatic Diagnostic Scale [Time Frame: Change from Baseline post traumatic diagnostic scale levels at average 6 months] [Designated as safety issue: No]
- Patient global impression of change [Time Frame: after on average 6 months of treatment] [Designated as safety issue: No]
- Recruitment potential [Time Frame: 6 months] [Designated as safety issue: No]

  % of patients eligible for inclusion that give written informed consent

- Retention rate [Time Frame: over average 6 months of treatment] [Designated as safety issue: No]

  % of patients that finish treatment, including pre- and post-evaluation

Enrollment: 40
Study Start Date: May 2013
Study Completion Date: December 2015
Primary Completion Date: November 2014 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: **Eye-Movement-Desensitization-Reprocessing** **Eye-Movement-Desensitization-Reprocessing**	Behavioral: **Eye-Movement-Desensitization-Reprocessing**
No Intervention: Treatment as usual (control group)	

treatment as usual	

Detailed Description:
The study explores the feasibility of Eye-Movement-Desensitization and Reprocessing (EMDR) in non-specific chronic back pain in a randomized controlled trial (RCT) with 6 months follow-up. The treatment consists of 12-sessions EMDR a 60 minutes using eye-movements for bilateral stimulation in addition to treatment as usual (TAU) that is compared to TAU alone.

Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- >= 18 years
- non-specific chronic low back pain >= 45 days/3 months
- high emotional distress caused by psychological trauma
- German language skills

Exclusion Criteria:

- specific causes of chronic back pain
- application for retirement pension pending
- ongoing psychotherapy
- severe physical or psychiatric comorbidity

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: NCT01850875

Locations

Germany

University Hospital Heidelberg
Heidelberg, Baden-Württemberg, Germany, 69120

Sponsors and Collaborators

University Hospital Heidelberg

Investigators

Principal Investigator: Wolfgang Eich, Prof. Dr. University Hospital Heidelberg

More Information

Additional Information:

Consortium LOGIN EXIT

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Tesarz J, Gerhardt A, Leisner S, Janke S, Hartmann M, Seidler GH, Eich W. Effects of eye movement desensitization and reprocessing (EMDR) on non-specific chronic back pain: a randomized controlled trial with additional exploration of the underlying mechanisms. BMC Musculoskelet Disord. 2013 Aug 30;14:256. doi: 10.1186/1471-2474-14-256.

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Health Authority: Germany: Federal Ministry of Education and Research

Keywords provided by University Hospital Heidelberg:
Eye-Movement-Desensitization and Reprocessing
EMDR

Chronic back pain
CBP
treatment

Additional relevant MeSH terms:
Back Pain
Pain
Neurologic Manifestations
Nervous System Diseases
Signs and Symptoms

ClinicalTrials.gov processed this record on August 16, 2016