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Recording Heart Rate Variability During Eye Movement Desensitisation Reprocessing With or Without Eye Movement (EMDR;PTSD)

This study has been withdrawn prior to enrollment.
(No participants recruited)

Sponsor:
University of Edinburgh

Collaborator:
NHS Tayside

Information provided by (Responsible Party):
University of Edinburgh

ClinicalTrials.gov Identifier:
NCT02565563

First received: September 21, 2015
Last updated: April 7, 2016
Last verified: September 2015
History of Changes

Purpose

The purpose of the study is to gain greater insight into **Eye Movement Desensitisation Reprocessing** (**EMDR**). **EMDR** is an NHS recommended treatment, which can significantly reduce trauma symptoms. There is some debate regarding how it actually works, however there is evidence to suggest that the eye movements component helps reduce anxiety and increase relaxation levels. To measure these arousal levels during **EMDR** previous research has used electrocardiography (ECG) to measure heart rate, which offers insight into the effectiveness of eye movements (EM). All studies to date have used ECG to measure arousal levels which requires technical knowledge to administer and interpret. Furthermore, applying electrodes to a patient experiencing PTSD may heighten anxiety. The present study will use new technology which is a small device that would be gently attached to the end of the patient's index finger. This device is very similar to one that measures oxygen levels in the blood and therefore is a very simple piece of equipment and should cause no discomfort to the patient. The study also requires patient's faces to be video recorded throughout and it will only be their face that is recorded. This is to match the stages of treatment (i.e. when EM starts and stops) to their corresponding arousal level outcome. The new technology will digitally measure the patient's anxious and relaxed arousal levels during EM and no EM treatment sessions. 10 NHS patients would be recruited to receive two treatment sessions; one with EM and one without and then continue with treatment as usual without any of the recording devices. EM and no EM phases occur at least three times within a treatment session and therefore several measurements can be taken and analysed.

Condition	Intervention
Post Traumatic Stress Disorder	Other: **Eye Movement Desensitisation Reprocessing** Device: HeartMath measuring Heart Rate Variability (HRV)

Study Type: Interventional
Study Design: Allocation: Non-Randomized
Intervention Model: Crossover Assignment
Masking: Open Label
Primary Purpose: Basic Science

Official Title: Digitally Recording Heart Rate Variability Via the Patient's Finger: Is There a Difference Between Eye Movements and no Eye Movements During **Eye Movement Desensitisation Reprocessing** Treatment for Post Traumatic Stress Disorder?

Resource links provided by NLM:

MedlinePlus related topics: Anxiety Post-Traumatic Stress Disorder

U.S. FDA Resources

Further study details as provided by University of Edinburgh:

Primary Outcome Measures:

- Heart Rate Variability (HRV) [Time Frame: up to 7 months] [Designated as safety issue: No]

This is the variation in the beat-to-beat interval and measures the sympathetic nervous system (SNS). A minimum of 3 arousal level (HRV) measurements will be taken within each treatment session. An average measurement will be calculated for each patient during each condition. Paired sample t-tests will be used to compare heart rate variability (arousal levels) outcomes between eye movements and no eye movements for each patient. A repeated measures ANOVA will be used to analyse any differences across each session of eye movements and no eye movements (containing a minimum of 3 phases in each session), to see if there is an improvement in HRV (i.e. a reduction in anxiety arousal and increase in relaxed arousal) over each session.

Secondary Outcome Measures:

- Subjective Units of Distress (SUDs) [Time Frame: up to 7 months] [Designated as safety issue: No]

  Do patients' self rating scores of distress (within EMDR treatment this is known as subjective units of distress [SUDs]) reduce as their anxiety levels reduce and their relaxation levels increase? A test of correlation will be conducted to determine the relationship between patients subjective units of distress and HRV.

Enrollment:	0
Study Start Date:	October 2015
Estimated Study Completion Date:	March 2016
Estimated Primary Completion Date:	February 2016 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: Eye Movements **Eye Movement Desensitisation Reprocessing** with eye movements (measuring Heart Rate Variability using HeartMath)	Other: **Eye Movement Desensitisation Reprocessing** The purpose of this study is not to assess the device itself. The new device will seek to measure heart rate variabilty during the administration of the treatment **EMDR**. It will measure the patients sympathetic nervous systems (anxiety arousal). Previous reseach studies have used Electrocardiography (ECG) and the purpose of this study is to determine whether or not this device will obtain similar findings as ECG has done. Device: HeartMath measuring Heart Rate Variability (HRV) This small device will be attached to the patients finger to allow their heart rate variability to be measured.
Active Comparator: No Eye Movements **Eye Movement Desensitisation Reprocessing** without eye movements (measuring Heart Rate Variability using HeartMath)	Other: **Eye Movement Desensitisation Reprocessing** The purpose of this study is not to assess the device itself. The new device will seek to measure heart rate variabilty during the administration of the treatment **EMDR**. It will measure the patients sympathetic nervous systems (anxiety arousal). Previous reseach studies have used Electrocardiography (ECG) and the purpose of this study is to determine whether or not this device will obtain similar findings as ECG has done. Device: HeartMath measuring Heart Rate Variability (HRV) This small device will be attached to the patients finger to allow their heart rate variability to be measured.

Show Detailed Description

Eligibility

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

Criteria

Inclusion Criteria:

- Patients on the waiting list for psychological treatment who meet criteria for PTSD and/or sub clinical PTSD.
- Patients over the age of 18.
- Patients able to give informed consent
- Single trauma event

Exclusion Criteria:

- Patients in other psychological treatment.
- Patients unable to provide informed consent
- Patients who are actively suicidal
- Patients who score above 30 on the dissociative experiences scale (DES).
- Difficulties with eye sight, where vision cannot be corrected with glasses or lenses (EMDR requires the patient to accurately follow their finger with their eyes)

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.

No Contacts or Locations Provided

More Information

Responsible Party:	University of Edinburgh
ClinicalTrials.gov Identifier:	NCT02565563 History of Changes
Other Study ID Numbers:	173479
Study First Received:	September 21, 2015
Last Updated:	April 7, 2016
Health Authority:	Scotland: Scottish Executive Health Department

Keywords provided by University of Edinburgh:
EMDR
Mechanisms
Eye Movement Desensitisation Reprocessing

Additional relevant MeSH terms:
Stress Disorders, Traumatic
Stress Disorders, Post-Traumatic
Trauma and Stressor Related Disorders
Mental Disorders

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