# EVEREST - «The assessment of EMDR* to treat post-traumatic-stress-disorder » Involvement of corticotropic and sympathetic axes.

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## General

### Identification

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| Detailed name | «The assessment of EMDR* to treat post-traumatic-stress-disorder » Involvement of corticotropic and sympathetic axes. |
| Sign or acronym | EVEREST |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | CNIL n°1654767v0 - CPP : 2009-A00685-52 (05.10.2009) - Afssaps : n°ID RCB 2009-A00685-52 (09.10.2009) |

### General Aspects

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| Medical area | Endocrinology and metabolism<br>Psychology and psychiatry |
| Pathology (details) | Assesment of a psychotherapy : EMDR (*Eye Movement Disensitization and Reprocessing) prognostic biomarker of remission |
| Keywords | Prospective study, psychiatry, naturalistic study, EMDR psychotherapy assessment, biological markers, corticotropic and sympathetic axes, salivary cortisol, metabolic marker, heart rate, cutaneous conductance, randomized study, multicenter study, psychiatric comorbidities., Post traumatic stress disorder, PTSD, clinical research, allostatic load |

### Scientific investigator(s) (Contact)

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| Unit | Inserm U1061 |
| Organization | INSERM |

## Collaborations

| | |
|---|---|
| Participation in projects, networks and consortia | Yes |
| Details | ABC of psychotraumas, Biological & clinic approches |

## Funding

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| Funding status | Public |
| Details | PHRC inter-régional (CHU de Montpellier) |

## Governance of the database

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| Sponsor(s) or organisation(s) responsible | Promoteur : Association audoise Sociale et Médicale ASM, Limoux |
| Organisation status | Private |
| Sponsor(s) or organisation(s) responsible | Financement : PHRC Inter-régional-CHU Montpellier |
| Organisation status | Public |
| Sponsor(s) or organisation(s) responsible | Coordination scientifique : Inserm U1061 |
| Organisation status | Public |

## Additional contact

# Main features

## Type of database

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| Type of database | Study databases |
| Study databases (details) | Longitudinal study (except cohorts) |
| Database recruitment is carried out by an intermediary | A selection of health institutions and services |

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| Database recruitment is is made on the basis of: | Another treatment or procedure |
| Database recruitment is carried out as part of an interventional study | Yes |
| Details | Performed at group level (clusters) |
| Additional information regarding sample selection. | - prospective study ; recruitment of all patients coming to the CMP(medical and psychological center) complying with the criteria requirements<br>- End of the recruitment : september 2013 |

## Database objective

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| Main objective | The main objective is to compare the effectiveness of EMDR psychotherapy and a supportive psychotherapy in chronic post-traumatic stress disorder patients, through a pragmatic-trial based on a daily practice of a psychiatry sector.<br>Secondary objectives are<br>1)To study the link between diurnal salivary cortisol secretion and post traumatic symptoms<br>11)Over all the participants in the survey both at the inclusion and the 3 months visits<br>12)Over all the EMDR group participants, one year after the beginning of the cares.<br>2)To study the link between salivary cortisol levels during the EMDR sessions and post traumatic symptoms at 3 months (group 1)<br>3)To study the link between neurovegetative excitation regulation during the EMDR sessions and post traumatic symptoms at 3 months (group 1)<br>4)To assess the EMDR psychotherapy effect on a midterm, one year after the first EMDR session. |
| Inclusion criteria | - Women and men aged 18-75 years<br>- Chronical PTSD patients (for more than 3 months, diagnosed by the CAPS scale/DSM IV criteria<br>- Patients who are not following a psychotherapy focused on PTSD<br>- Patients that never have followedr a CBT (Cognitive behavioral therapy) or a EMDR psychotherapy focused on the traumatic memory<br>- Patients without psychotropic treatment or who have a stabilized treatment for at least 3 months. |

## Population type

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| Age | Adulthood (19 to 24 years)<br>Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years) |

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| | Elderly (65 to 79 years) |
| Population covered | Sick population |
| Gender | Male<br>Woman |
| Geography area | Regional |
| French regions covered by the database | Languedoc-Roussillon Midi-Pyrénées |
| Detail of the geography area | - 2 centers : CMP (Medical and psychological center) of Narbonne and Lezignan-Corbières |

## Data collection

### Dates

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| Date of first collection (YYYY or MM/YYYY) | 05/2010 |
| Date of last collection (YYYY or MM/YYYY) | 09/2014 |

### Size of the database

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| Size of the database (number of individuals) | < 500 individuals |
| Details of the number of individuals | - 80 |

### Data

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| Database activity | Data collection completed |
| Type of data collected | Clinical data<br>Declarative data<br>Biological data |
| Clinical data (detail) | Medical registration |
| Declarative data (detail) | Paper self-questionnaire<br>Face to face interview |
| Biological data (detail) | - Blood samples at visit 1 ; Total cholesterol, HDL, LDL, triglyceride, HbA1C - Salivary cortisol samples ; visit 1, psychotherapy sessions, visit 2 and 3 - Heart rate and cutaneous conductance ; visit 1, psychotherapies sessions, visit 2 and 3 - Morphometric measurements at visit 1 ; blood |

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| | pression, weight and size, the waist to hip ratio |
| Presence of a biobank | No |
| Contents of biobank | Fluids (saliva, urine, amniotic fluid, ?) |
| Health parameters studied | Health event/morbidity<br>Health care consumption and services<br>Others |
| Care consumption (detail) | Medical/paramedical consultation<br>Medicines consumption |
| Other (detail) | resilience |
| **Procedures** | |
| Data collection method | - self and administrated-reported scales, clinical administration and biological samples ; manual data entry (from paper documents) |
| Classifications used | DSM IV |
| Participant monitoring | Yes |
| Details on monitoring of participants | - Pré-inclusion visit (until 7 days before visit 1) ; self and administrated-reported scales - Visit 1 (day 1) ; self and administrated-reported scales, clinical examination, socio-demographic data, blood and salivary samples, Heart rate and cutaneous conductance, Morphometric measurements, - Psychotherapies sessions (2 to 7 sessions) ; self-reported scales, salivary samples, heart rate and cutaneous conductance - Visit 2 (3 months after visit 1) ; self and administrated-reported scales, salivary samples, heart rate and cutaneous conductance - Visit 3 (1 year after visit 1) ; self and administrated-reported scales, salivary samples, heart rate and cutaneous conductance |
| Links to administrative sources | No |
| **Promotion and access** | |
| **Promotion** | |
| **Access** | |
| Terms of data access (charter for data provision, format of data, availability delay) | contact the scientist in charge |
| Access to aggregated data | Access on specific project only |

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| Access to individual data | Access on specific project only |