

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

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General

Identification

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

Medical area	Endocrinology and metabolism Psychology and psychiatry
Pathology (details)	Assesment of a psychotherapy : EMDR (*Eye Movement Desensitization 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
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Scientific investigator(s) (Contact)

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Organization	INSERM

Collaborations

Participation in projects, networks and consortia Yes

Details ABC of psychotraumas, Biological & clinic approches

Funding

Funding status Public

Details PHRC inter-régional (CHU de Montpellier)

Governance of the database

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

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

Database recruitment 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
- End of the recruitment : september 2013

Database objective

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. Secondary objectives are

- 1) To study the link between diurnal salivary cortisol secretion and post traumatic symptoms
- 11) Over all the participants in the survey both at the inclusion and the 3 months visits
- 12) Over all the EMDR group participants, one year after the beginning of the cares.
- 2) To study the link between salivary cortisol levels during the EMDR sessions and post traumatic symptoms at 3 months (group 1)
- 3) To study the link between neurovegetative excitation regulation during the EMDR sessions and post traumatic symptoms at 3 months (group 1)
- 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
- Chronical PTSD patients (for more than 3 months, diagnosed by the CAPS scale/DSM IV criteria
- Patients who are not following a psychotherapy focused on PTSD
- Patients that never have followed a CBT (Cognitive behavioral therapy) or a EMDR psychotherapy focused on the traumatic memory
- Patients without psychotropic treatment or who have a stabilized treatment for at least 3 months.

Population type

Age Adulthood (19 to 24 years)
Adulthood (25 to 44 years)
Adulthood (45 to 64 years)

Elderly (65 to 79 years)

Population covered Sick population

Gender Male
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

Date of first collection (YYYY or MM/YYYY) 05/2010

Date of last collection (YYYY or MM/YYYY) 09/2014

Size of the database

Size of the database (number of individuals) < 500 individuals

Details of the number of individuals - 80

Data

Database activity Data collection completed

Type of data collected Clinical data
Declarative data
Biological data

Clinical data (detail) Medical registration

Declarative data (detail) Paper self-questionnaire
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

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
Health care consumption and services
Others

Care consumption (detail) Medical/paramedical consultation
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

Access to individual data

Access on specific project only