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 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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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 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 followedr 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