

Intensive care by osteopathy for victims of road traffic accidents (RTA) (AIVIO: Aide Intensive aux Victimes dAccident de la Voie Publique (AVP) par Ostéopathie)

Submission date 24/03/2011	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 19/05/2011	Overall study status Completed	☐ Protocol
Last Edited 19/05/2011	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

AIVIO/CHNDRF/0708

Study information

Scientific Title

Intensive care by osteopathy for victims of road traffic accidents (RTA) (AIVIO: Aide Intensive aux Victimes d'Accident de la Voie Publique (AVP) par Ostéopathie): a single centre, pilot, prospective, randomised controlled trial

Acronym

AIVIO (Aide Intensive aux Victimes par Ostéopathie)

Study objectives

1. The sensory stimuli developed by functional osteopathy technique are thought to produce similar effects to sensory stimuli used in eye movement desensitisation and reprocessing (EMDR), inducing the same ponto-geniculo-occipital (PGO) waves that potentially activate the transfer of hippocampal traumatic memory information to the semantic cortex.
2. Functional osteopathy appears to produce additional therapeutic mechanisms: somatic work appears to reactivate cell assemblies, useful when verbal reconstruction is difficult or impossible. Without verbal induction, recall occurs when psychic resistance lowers, protecting fragile victims from potential depressive or psychotic decompensation. The tactile dialogue is respectful of the body's resistance and in this manner rapidly leads to a feeling of security, narcissistic reassurance and peaceful dissociation. These elements of the therapeutic context bring about recall of the traumatic information without anxiety, further eliminating avoidance strategies which maintain post-traumatic stress disorder (PTSD).
3. Finally, myofascial tensions acquired from the accident (whiplash in particular) potentially contribute to neurovegetative disorders, to sensitisation of the hypothalamic-pituitary adrenal axis (HPA) and to persistent pain. Eliminating these mechanical tensions relieves muscular skeletal pain, itself having the potential to produce catecholaminergic and glutamatergic disorders.
4. The psychic and physical action of functional osteopathy could thus potentially contribute to regulating pathologically low cortisol levels of PTSD.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Ethics Committee of the Clinical Psychology Research Unit of the UCL (Université Catholique de Louvain) approved on 22nd March 2006.
2. Ethics Committee of the hospital, CHNDRF of Charleroi (Belgium) approved on 20th June 2006, ref: OM/100

Primary study design

Interventional

Study design

Single centre pilot prospective randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Post-traumatic stress disorder

Interventions

Treatment group 1: trauma victims (11 people), two men aged between 49 and 51 and nine women aged between 25 and 56.

Treatment involving 10 sessions of functional osteopathy, of one hour each, spaced a minimum of 15 days apart.

As opposed to structural osteopathy which seeks to restore skeletal alignment by what is known as high velocity and low amplitude cracking and manipulations of the joints, the mode of action of functional osteopathy is to retrace the lesion without irritation by way of meticulous adjustment of the connective tissue (including musculoskeletal structures) to balance tensions. While structural osteopathy may be described in easily identifiable and specific techniques, the functional approach relies on a true tactical dialogue with the tissues. Once the therapist has brought the tense tissues to their position of least tension in the three dimensions of space (front/back, right/left, superficial/deep), these myofascial structures release tension which the osteopath and often times the patient can perceive.

Control group 2: RTA victims on the waiting list, three women between 23 and 63

Control group 3: Young volunteers in good health and with no anxiety disorders, four women aged 23 to 30. Serious stress events affected three of them during the research study.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Post-traumatic Stress Disorder Checklist Scale (PCLS)
2. Salivary cortisol (IBL - AMERICA Salivary Cortisol HS ELISA Kit, a solid phase enzyme-linked immunosorbent assay based on the principle of competitive binding), measured twice a day for the 28 days before and after the treatment

Key secondary outcome(s)

1. Quality of life (Medical Outcome Survey SF-36) measured at each session
2. Pain: EVA and the item bodily pain (MOS SF-36) measured at each session
3. Heart rate measured at each session
4. Dissociation (Dissociative Experience Scale - DES) measured once before and once after the treatment
5. Depression (Beck depression Inventory 21) measured once before and once after the treatment
6. Non traumatic anxiety disorders (phobic disorders, panic attacks, generalized anxiety scale - PPGA) measured once before and once after the treatment
7. Alexithymia (Bermond and Vorst Alexithymia Questionnaire- BVAQ) measured once before and once after the treatment

Completion date

17/12/2008

Eligibility

Key inclusion criteria

1. Recent road traffic accident victims
2. Positive test for PTSD (PCLS>44) over 6 months after the RTA
3. Accept saliva tests: 2 daily saliva samples, one on waking and the other 30 minutes after the first, on an empty stomach and without having smoked or brushed teeth. Over a period of 28 days before and after treatment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. People under 18 years of age
2. People under pretraumatic corticotherapy
3. People whose alcohol consumption regularly exceeds two glasses for women or three glasses for men
4. People who did not provide the saliva samples

Date of first enrolment

01/03/2007

Date of final enrolment

17/12/2008

Locations**Countries of recruitment**

Belgium

France

Study participating centre

99, rue du Petit Château

Charenton Le Pont

France

94220

Sponsor information

Organisation

Catholic University of Louvain (Université Catholique de Louvain) (Belgium)

ROR

<https://ror.org/02495e989>

Funder(s)**Funder type**

Other

Funder Name

Investigator initiated and funded (Belgium)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration