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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

Registration date
19/05/2011

Last Edited
19/05/2011

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AIVIO/CHNDRF/0708

Study information

Scientific Title
Intensive care by osteopathy for victims of road traffic accidents (RTA) (AIVIO: Aide Intensive aux Victimes dAccident 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 bodys 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 pathognomonically 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

Study design
Single centre pilot prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
1. Quality of life (Medical Outcome Survey SF-36) meassured 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

Overall study start date
01/03/2007

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

Age group
Adult

Sex
Both

Target number of participants
Planned sample size: 60

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)

Sponsor details
Place de l'Université
Louvain-la-Neuve
Belgium
1348

Sponsor type
University/education

ROR
https://ror.org/02495e989

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Belgium)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration