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A brief and early psychological intervention for individuals exposed to psychological trauma

Submission date	Recruitment status	[ ] Prospectively registered
27/08/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/10/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/06/2019	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Alain Brunet

Contact details
Douglas Hospital Research Center
Perry Building (E 4129)
6875
LaSalle Boulevard
Montréal
Canada
H4H 1R3
+1 514 761 6131 x 4348
alain.brunet@douglas.mcgill.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SR-4370

Study information

Scientific Title
A brief and early psychological intervention for individuals exposed to psychological trauma

Study objectives
A time by group interaction is expected whereby self-reported symptoms of posttraumatic stress disorder (PTSD) will be less severe in the intervention group than in the no intervention control group at the post-test, but not at the pre-test or at mid-treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
McGill's Research and Ethic Board. Date of approval: 09/09/2002 (protocol number: A01-B03-02A)

Study design
Single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Posttraumatic stress disorder

Interventions
This is a single-blind, randomised controlled trial with a treated group and another group on a waiting list completing the periodic assessments only.

This two-session dyadic intervention includes elements of psychoeducation and motivational interviewing, and targets communication between the patient and significant other, aiming to facilitate support, promote bi-directional disclosure, reduce disclosure-constraining behaviours, and improve coping. It promotes the disclosure of thoughts and emotions about the trauma in the natural environment of the dyad while attempting to reduce social constraints on disclosure and negative social support interactions. The intervention is led by a social worker or a nurse trained and supervised every second week by a clinical psychologist. The initial 90-minute session takes place within the first few weeks after the traumatic event. A 75-minute follow-up meeting is scheduled two weeks later.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
PTSD self-reported symptoms as measured by the Impact of Event Scale Revised. We measured PTSD symptoms on average 26 days after trauma exposure (baseline, before treatment), then on average 40 days post-trauma at mid-treatment (after one treatment session), and 90 days after trauma exposure (a time when one can diagnose chronic PTSD), and then again 2 years after trauma exposure.

Secondary outcome measures
Negative social support. (It was hypothesised that the treatment would decrease the provision of negative social support from the significant other toward the trauma victim.). This was assessed using the Social Constraints Scale (SCS). Timepoints: 26 days (on average) after trauma exposure (baseline, before treatment), 40 days post-trauma at mid-treatment (after one treatment session), 90 days and 2 years after trauma exposure.

Overall study start date
09/09/2002

Completion date
14/03/2008

Eligibility

Key inclusion criteria
1. Both males and females, adults aged 18-65
2. Patients who present to the emergency room because of trauma exposure (in the last 10 days). Trauma is defined as an event eliciting a peritraumatic reaction of fear, helplessness, or horror.
3. Patients who speak either French or English
4. Medication free at trial onset
5. Patients who are in a medically stable condition
6. Patients who live in the Montreal metropolitan area
7. Patients who have a significant other whom they can bring to the therapy session
8. Patients who succeed at making an appointment with the therapist in a timely manner

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
66

Total final enrolment
74

Key exclusion criteria
1. Patients who have a suspected or confirmed traumatic brain injury
2. Patients who have a lifetime diagnosis of psychosis, substance/alcohol dependence, bipolar disorder, or mental retardation
3. Patients who have been clinically depressed in the last 2 years

Date of first enrolment
09/09/2002

Date of final enrolment
14/03/2008

Locations

Countries of recruitment
Canada

Study participating centre
Douglas Hospital Research Center
Montréal
Canada
H4H 1R3

Sponsor information

Organisation
Québec Fund for Research on Society and Culture (FQRSC) (Canada)

Sponsor details
140, Grande Allée Est
Bureau 470
Québec
Canada

G1R 5M8
+1 418 643 7582
fqrsc@fqrsc.gouv.qc.ca

Sponsor type
Government

Website
http://www.fqrsc.gouv.qc.ca

ROR
https://ror.org/00shpc021

Funder(s)

Funder type
Government

Funder Name
Québec Fund for Research on Society and Culture (Fonds Québécois de la Recherche sur la Société et la Culture) (FQRSC), formerly known as Québec Council for Social Research (Conseil Québécois de la Recherche Sociale) (CQRS) (Canada) (ref: SR-4370)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/08/2013	28/06/2019	Yes	No