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Effectiveness of trial-based therapy in post-traumatic stress disorder

Submission date
27/05/2014

Recruitment status
No longer recruiting

Registration date
19/06/2014

Overall study status
Completed

Last Edited
25/06/2020

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

Background and study aims?
Post-traumatic stress disorder (PTSD) is an anxiety disorder caused by frightening, stressful or traumatic events. Symptoms include nightmares, flashbacks, feelings of isolation and difficulty in sleeping and concentrating. Prolonged exposure therapy is one method that has been shown to be successful in treating patients suffering from PTSD. It works by getting the patient to re-experience the event by remembering it, and engaging with it, when faced with reminders (triggers) of the trauma, rather than try and avoid thinking about the issue. Trial-based therapy, on the other hand, is based on some elements of cognitive-based therapy, in which it helps patients to manage their PTSD though changing the way they think and behave. The trial-based thought record is central to trial-based therapy; patients are encouraged to engage in a simulation of the judicial process in order to challenge their negative thinking and develop more positive and functional beliefs about themselves. This study compares these two forms of therapies and asks whether trial-based therapy is as effective as exposure therapy.

Who can participate?
Adult chronic PTSD patients that have enrolled in the Anxiety Program and the Psychotherapy Service of the Department and Institute of Psychiatry, University of Sao Paulo.

What does the study involve?
Each patient is randomly placed into one of two groups. Those in group 1 receive trial-based therapy. Those in group 2 receive exposure therapy. Patients in both groups will have therapy every week for 11 weeks, followed by therapy every 2 weeks for 4 weeks and, finally, a follow-up session 3 months later. Each therapy session is an hour long and held in the same place and day of the week. Patients that do not wish to participate in the therapy sessions are given drug treatment and will be followed up after 13 weeks and again after 3 months.

Where is the study run from?
Department and Institute of Psychiatry, University of São Paulo (Brazil)

When is the study starting and how long is it expected to run for?
January 2014 to March 2015

Who is funding the study?
The Anxiety Program (AMBAN) at the Department and Institute of Psychiatry, University of São Paulo (Brazil)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
U1111-1147-1336

Study information

Scientific Title
Effectiveness of trial-based therapy in post-traumatic stress disorder: a randomised clinical trial

Study objectives
1. Trial-based therapy is more effective in the treatment of PTSD than exposure
2. Patients with chronic PTSD have worse outcome than those with subclinical or partial PTSD
3. Patients who choose not to do psychotherapy and receive pharmacotherapy treatment only have a worse outcome

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee for Analysis of Research Projects (Comissão de Ética para Análise de Projetos de Pesquisa) - CAPPesq, 8/5/2013, ref. 09229413300000068

Study design
Randomised clinical trial

Primary study design

Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic, subclinical or partial post-traumatic stress disorder

Interventions
72 patients enrolled in the Anxiety Program and the Psychotherapy Service of the Department and Institute of Psychiatry, University of São Paulo with the diagnosis of chronic PTSD will be invited to participate in this study. They will be assessed through a semi-structured clinical interview about the trauma. After admission to the Institute of Psychiatry they will be interviewed by psychiatrists with the PTSD section of the SCID to ensure the presence of the diagnosis according to DSM-IV. Participants will receive explanations about the therapies and sign the informed consent. If necessary they will receive drug treatment and followed by these professionals. They will also receive the self-assessment scales and will be interviewed and assessed using the Clinical Global Impression (CGI) score.

The 72 participants will be randomly assigned to one of the two following treatment groups and will be attended by other psychologists and psychiatrists specially trained.
1. Group 1 - will receive treatment by trial-based therapy.
2. Group 2 - will be treated with exposure therapy.

The duration of the treatment will be made up as follows:
1. Therapy every week for 11 weeks followed by:
2. Therapy every 2 weeks for 4 weeks
3. Follow up session at 3 months

Each psychotherapy session will be one hour long and held at the same location and day of the week. The two forms of therapy will be held at the same location and day of the week.

The trial will involve six psychotherapists trained in cognitive behavioral therapy and in the use of all techniques. Each will be responsible for the treatment of twelve patients. Patients will be evaluated by a physician at the beginning, at least once a month or more if indicated, at the end of treatment and three months after its completion. These will be trained in the use of the SCID section on PTSD and the use of DSM IV TR and the CGI scale. The effectiveness of the treatment will be assessed by the following criteria:
1. Fall of 15 points in Davidson Trauma Scale
2. Score 0 or 1 on the Clinical Global Impression rating
3. Score lower than 8 on the Beck Depression Inventory
4. Number of dropouts from treatment

The quality of treatment offered will be evaluated by experienced evaluators from three recorded sessions from each therapist.The evaluation instruments will be done again in session 13, and after the follow-up (after 3 months). Patients who choose only the pharmacological treatment will be evaluated on the same dates.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
An assessment will be carried out with self questionnaires applied prior to initiating therapy after 13 sessions and after 3 months of completion of therapy.This will be used as a criterion of effectiveness a 15 points change in Davidson Trauma Scale according to the literature.

Key secondary outcome(s))
1. Changes in scores on the Beck Depression and Anxiety Inventories (BDI and BAI)
2. Clinical Global Impression Scale (CGI)
3. Automatic Thoughts Questionnaire (ATQ 30)
4. Dysfunctional Attitudes Questionnaire (DAS)
5. SF-36
6. Number of treatment drop outs

Completion date
30/03/2015

Eligibility

Key inclusion criteria
1. Both genders
2. Age 18 and 65 years
3. Able to write and follow the instructions of the protocol
4. Give consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. People with imminent risk of suicide, self-mutilation behaviours (cutting, burning, hurting themselves deliberately)
2. Psychosis not stabilized with medication
3. Risk of suffering further violence
4. Lack of memory about the traumatic event
5. Abuse or dependence of alcohol and drugs

Date of first enrolment
30/01/2014

Date of final enrolment
30/03/2015

Locations

Countries of recruitment
Brazil

Study participating centre
Dr. Ovídio Pires de Campos, 785
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Sponsor information

Organisation
Anxiety Program (Amban) at the Institute of Psychiatry Faculty of Medicine University of São Paulo (Brazil)

ROR
https://ror.org/036rp1748

Funder(s)

Funder type
University/education

Funder Name
The Anxiety Program (Amban) at the Institute of Psychiatry Faculty of Medicine, University of São Paulo (Brazil)

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes