

The efficacy of an intervention for post traumatic stress disorder among illicit drug users

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|--------------------------|----------------------------------|--|
| Submission date | Recruitment status | <input type="checkbox"/> Prospectively registered |
| 02/04/2007 | No longer recruiting | <input type="checkbox"/> Protocol |
| Registration date | Overall study status | <input type="checkbox"/> Statistical analysis plan |
| 15/05/2007 | Completed | <input checked="" type="checkbox"/> Results |
| Last Edited | Condition category | <input type="checkbox"/> Individual participant data |
| 16/08/2012 | Mental and Behavioural Disorders | |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

NHMRC Project Grant 455209

Study information

Scientific Title

Study objectives

Participants who receive an integrated treatment for their Post Traumatic Stress Disorder (PTSD) and substance use (treatment group) will demonstrate greater reductions in PTSD symptoms and substance use compared to those who receive standard care for their substance use alone (control group).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval granted by the University of New South Wales (HREC 06064).

Study design

Randomised controlled trial.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Post traumatic stress disorder and substance use disorders

Interventions

The treatment group will receive an integrated treatment for PTSD and substance dependence called 'Concurrent Treatment with Prolonged Exposure'. Concurrent Treatment with Prolonged Exposure involves 13 individual weekly 90 minute sessions with a clinical psychologist, incorporating Cognitive Behavioural Therapy (CBT) for substance use and PTSD. CBT for PTSD includes cognitive therapy, imaginal and in vivo exposure.

The control group will receive treatment as usual (standard care) for their substance use.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Reduction in PTSD symptoms and drug use will be measured at 6 weeks, 3 and 9 months post-baseline.

Key secondary outcome(s)

Improvements in other treatment outcomes including their overall physical and mental health will also be measured at 6 weeks, 3 and 9 months post-baseline using the following:

1. Short Form 12 questionnaire (for assessment of general physical and mental health)
2. Beck Depression Inventory II
3. State Trait Anxiety Inventory

Completion date

31/12/2009

Eligibility

Key inclusion criteria

1. 18 years of age or older
2. Lifetime exposure to at least one traumatic event
3. Screen positive for current (past month) PTSD
4. Use of drugs other than alcohol at least four times in the past month
5. Literate in English
6. Willing to give locator information

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Current suicidality or recent self-harming behaviours
2. Chronic psychosis
3. Cognitive impairment sufficient to interfere with therapy

Date of first enrolment

23/04/2007

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

Australia

Study participating centre

National Drug & Alcohol Research Centre, University of NSW

Sydney

Australia

2052

Sponsor information

Organisation

National Health and Medical Research Council (Australia)

ROR

<https://ror.org/011kf5r70>

Funder(s)

Funder type

Research council

Funder Name

National Health and Medical Research Council (Australia)

Alternative Name(s)

National Health and Medical Research Council, Australian Government, NHMRC National Health and Medical Research Council, NHMRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Australia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 15/08/2012 | | Yes | No |