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

Submission date
02/04/2007

Recruitment status
No longer recruiting

Registration date
15/05/2007

Overall study status
Completed

Last Edited
16/08/2012

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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
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

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

Secondary outcome measures
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

Overall study start date
23/04/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

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)

Sponsor details
GPO Box 1421
Canberra
Australia
2601
grantnet.help@nhmrc.gov.au

Sponsor type
Research council

Website
http://www.nhmrc.gov.au/

ROR
https://ror.org/011kf5r70

Funder(s)

Funder type
Research council

Funder Name
National Health and Medical Research Council (Australia)

Alternative Name(s)
NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

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	15/08/2012		Yes	No