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

Submission date	Recruitment status  No longer recruiting	Prospectively registered	
02/04/2007		☐ Protocol	
Registration date 15/05/2007	Overall study status Completed	Statistical analysis plan	
		[X] Results	
Last Edited	Condition category	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

#### Contact name

Dr Katherine Mills

#### Contact details

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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

#### 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

# 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