

# Tryptophan depletion in patients with Selective Serotonin Reuptake Inhibitor (SSRI)-remitted anxiety disorders

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<b>Registration date</b> 10/05/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/01/2021	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

RA/4/1/1193, ACTRN12609000170224

## Study information

Scientific Title

Tryptophan depletion in patients with Selective Serotonin Reuptake Inhibitor (SSRI)-remitted anxiety disorders

### **Study objectives**

Primary hypotheses:

1. Tryptophan depletion (TD) will cause transient symptom relapse in SSRI-remitted GAD patients, but only when challenged with the 7.5% CO<sub>2</sub> provocation paradigm (Study 2)
2. OCD patients well on SSRIs will not relapse spontaneously when undergoing TD but will suffer a significant worsening of anxiety when exposed to a personalised phobic stimulus (Study 1)

Secondary hypotheses:

1. TD will have a greater impact upon women than men, according to primary outcome measures
2. Women will experience more nausea on the occasion that they have the tryptophan-restored (control) drink than on the tryptophan-depleted occasion
3. Transient depressive symptoms will be seen in subjects with a past history of depressive illness, despite the absence of a current or recent diagnosis of a depressive disorder

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Not Specified

### **Health condition(s) or problem(s) studied**

Obsessive-compulsive disorder (OCD); Generalised anxiety disorder (GAD).

### **Interventions**

1. Tryptophan depletion (double-blind crossover) vs tryptophan restored intervention
2. Disorder specific provocation, viz:
  - a. 20 min 7.5% CO<sub>2</sub> inhalation or air (GAD)
  - b. Exposure to a known anxiogenic stimulus (OCD)

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome(s)**

Study 1: Visual Analogue Scales (VAS), The Spielberger State Anxiety Inventory (STAI), tryptophan levels, c. Profile of Mood States (POMS), Yale-Brown Obsessive Compulsive Scale (Y-

BOCS)

Study 2: Visual Analogue Scales (VAS), The Spielberger State Anxiety Inventory (STAI), tryptophan levels, c. Profile of Mood States(POMS), Generalised Anxiety Disorder Inventory (GADI)

**Key secondary outcome(s)**

Beck Depression Inventory (BDI), Blood pressure/heart rate data, Swedish universities Scales of Personality (SSP).

**Completion date**

31/12/2006

## **Eligibility**

**Key inclusion criteria**

Study 1: Primary diagnosis of obsessive-compulsive disorder (OCD), currently remitted with SSRI therapy

Study 2: Primary diagnosis of generalised anxiety disorder (GAD), currently remitted with SSRI therapy

Aged 18-65

Able and willing to give informed consent prior to participation

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

65 years

**Sex**

All

**Total final enrolment**

12

**Key exclusion criteria**

1. No significant co-morbid anxiety disorder or other psychiatric disorder including alcohol or drug dependence
2. No major depressive episode with past 6 months
3. No significant other illness
4. No significant other medication therapy
5. No psychological therapy applied this episode

**Date of first enrolment**

01/07/2005

**Date of final enrolment**

31/12/2006

## **Locations**

**Countries of recruitment**

Australia

**Study participating centre**

School of Psychiatry and Clinical Neurosciences (M521)

Perth

Australia

6009

## **Sponsor information**

**Organisation**

Raine Medical Research Foundation (Australia)

**ROR**

<https://ror.org/04agdqh30>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Raine Priming Grant 2005-6.

## **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?
<a href="#">Results article</a>	results	01/02/2010	12/01/2021	Yes	No