

# A randomised controlled trial of occupational therapy led lifestyle treatment routine general practitioner treatment of panic disorder presenting in primary care

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/04/2008	<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

Mr Rod Lambert

### Contact details

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## Additional identifiers

### Protocol serial number

Lambert HSR/0500/1

## Study information

## **Scientific Title**

### **Study objectives**

To evaluate the cost-effectiveness of an Occupational Therapists led lifestyle treatment for patients presenting with panic disorder, compared with routine GP care. It will be monitored by a project board consisting of experts in clinical trials, panic disorder, general practice, occupational therapy and health economics, from Norfolk, Cambridgeshire and Oxford. The subject group will be patients presenting with panic disorder, with or without agoraphobic symptoms, at participating GP surgeries, between the ages of 16 and 65 years. Following a pilot study of 10 patients in each study arm, the main sample size followed through to analysis will be 85 in each arm of the study.

### **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)**

Treatment

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

Panic disorder

### **Interventions**

1. Occupational therapy led lifestyle treatment that assesses, plans and monitors lifestyle change over 10 intervention sessions
2. Routine GP care

### **Intervention Type**

Other

### **Phase**

Not Specified

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

1. Anxiety Disorders Interview Schedule for DSM-IV (ADIS-IV)
2. Self-report diary sheets recording frequency and severity of panic attacks
3. Beck Depression Inventory II
4. Beck Anxiety Inventory
5. Lifestyle Behaviour Index
6. 36-item short form health survey (SF-36)
7. Fear Questionnaire

**Key secondary outcome(s)**

Self-completion diary sheets which will record:

1. Fluid intake
2. Diet
3. Smoking
4. Exercise
5. Mood

**Completion date**

01/03/2003

**Eligibility****Key inclusion criteria**

1. Patients presenting with panic disorder between 16 and 65 years of age
2. Meet Diagnostic and Statistical Manual of Mental Disorders, Fourth edition (DSM-IV) criteria for panic disorder (from Anxiety Disorders Interview Schedule [ADIS-IV])
3. Panic is not considered secondary to another health problem
4. Stable medication for anxiety/depression for one month prior to referral

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

No identifiable lifestyle factors above a stated baseline level.

**Date of first enrolment**

01/05/2000

**Date of final enrolment**

01/03/2003

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**  
**School of Occupational Therapy & Physiotherapy**  
Norwich  
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NR4 7TJ

## Sponsor information

**Organisation**  
NHS R&D Regional Programme Register - Department of Health (UK)

## Funder(s)

**Funder type**  
Government

**Funder Name**  
NHS Executive Eastern (UK)

## 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	01/04/2007		Yes	No