

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

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

Secondary outcome measures

Self-completion diary sheets which will record:

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

Overall study start date

01/05/2000

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

Age group

Adult

Sex

Both

Target number of participants

200

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

England

United Kingdom

Study participating centre

School of Occupational Therapy & Physiotherapy

Norwich

United Kingdom

NR4 7TJ

Sponsor information

Organisation

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

Sponsor details

The Department of Health

Richmond House

79 Whitehall

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United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive Eastern (UK)

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	01/04/2007		Yes	No