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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

Registration date
23/01/2004

Overall study status
Completed

Last Edited
11/04/2008

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

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

Primary study design
Interventional

Study design
Randomised controlled trial

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 ll
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
United Kingdom
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?
Results article	Results	01/04/2007		Yes	No