

Cost-effectiveness of an optimised care model for patients with anxiety disorders in primary care

Submission date 08/01/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 17/02/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/11/2013	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
Prof Hans-Helmut König

Contact details
University of Leipzig
Health Economics Research Unit
Department of Psychiatry
Liebigstr. 26
Leipzig
Germany
04103

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
93200-061

Study information

Scientific Title

Cost-effectiveness of an optimised care model for patients with anxiety disorders in primary care: a cluster randomised controlled trial

Study objectives

Many patients with anxiety disorders do not receive accurate diagnosis or adequate treatment in primary care and cause high medical costs due to costly medical testing or the use of inappropriate and expensive emergency services. The main aim was to analyse the cost-effectiveness of an optimised care model for anxiety disorders in primary care that consisted of an intervention primarily targeted at primary care physicians.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Study protocol was approved by the ethics committee of the University of Leipzig in August 2004

Study design

Cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied

Anxiety disorders

Interventions

The intervention consisted of a specific training for GPs combined with an offer of consultation to the GPs for specific anxiety patients. The intervention aimed at improving GPs diagnostic and therapeutic knowledge and skills through a cognitive behavioural therapy (CBT) approach as used in psychiatry.

Follow-up occurred at 6-months and 9-months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Becks Anxiety Inventory (BAI)
2. Direct costs (raised with German Version of Client Sociodemographic and Service Receipt [CSSRI])

Secondary outcome measures

1. WHO Quality of Life Assessment (WHOQOL BREF)
2. Health outcomes questionnaire (EQ-5D)
3. Becks Depression Inventory (BDI)
4. Indirect costs (raised with German Version of Client Sociodemographic and Service Receipt [CSSRI])

Overall study start date

01/08/2005

Completion date

30/04/2007

Eligibility

Key inclusion criteria

1. Patients screened positive for one of the following anxiety disorders according to the criteria of the World Health Organization (WHO) International Classification of Diseases - version 10 (ICD-10):
 - 1.1. Social phobias (F40.1)
 - 1.2. Panic disorder [episodic paroxysmal anxiety] (F41.0)
 - 1.3. Generalized anxiety disorder (F41.1)
 - 1.4. Anxiety disorder, unspecified (F41.9)
2. Evaluated by German version of the Patient Health Questionnaire (PHQ-D)
2. Between 18 and 65 years of age

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

389 respondents at baseline - intervention group (201 patients in 23 practices); control group (188 patients in 23 practices)

Key exclusion criteria

1. Terminally ill
2. Suicidal
3. Cognitively impaired
4. Insufficient command of the German language

Date of first enrolment

01/08/2005

Date of final enrolment

30/04/2007

Locations**Countries of recruitment**

Germany

Study participating centre

University of Leipzig

Leipzig

Germany

04103

Sponsor information**Organisation**

Federal Ministry of Education and Research (Germany)

Sponsor details

Projektträger im DLR

Heinrich-Konen-Straße 1

Bonn

Germany

53227

Sponsor type

Government

Website

<http://www.dlr.de/pt>

ROR

Funder(s)

Funder type

Government

Funder Name

German Centre for Aerospace (Deutsches Zentrum für Luft- und Raumfahrt e.V.) (ref: DLR /01GL0502)

Funder Name

Federal Ministry for Education and Research (Bundeministerium für Bildung und Forschung [BMBF])

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	01/10/2009		Yes	No
Results article	results on cost effectiveness	01/10/2009		Yes	No
Results article	results	05/05/2010		Yes	No