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A randomised controlled trial to evaluate the efficacy and cost-effectiveness of counselling in patients with chronic depression and anxiety

Submission date
25/04/2003

Recruitment status
No longer recruiting

Registration date
25/04/2003

Overall study status
Completed

Last Edited
11/07/2019

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 93/07/68

Study information

Scientific Title
A randomised controlled trial to evaluate the efficacy and cost-effectiveness of counselling in patients with chronic depression and anxiety

Study objectives
To examine the effectiveness and cost-effectiveness of short-term counselling in general practice for patients with chronic depression or combined depression and anxiety, compared with general practitioner (GP) care alone.

Please note that the target number of participants was added as of 26/08/2009.

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
Mental and behavioural disorders: Depression, anxiety, neuroses

Interventions
A randomised controlled trial and economic evaluation with an initial assessment at randomisation and follow-ups at 6 and 12 month. The study used 9 general practices that were well-established participants of the Derbyshire counselling in general practice scheme, and already had a counsellor in the practice team.
The experimental group received usual GP treatment and were also referred to an experienced well-qualified counsellor attached to their general practice. Of the 8 counsellors, 2 practiced cognitive behavioural therapy (CBT) and 6 had a psychodynamic approach. The controls were

referred back to their GP for routine treatment. There were no restrictions regarding the treatment that could be used, except that GPs could not refer controls to practice counsellors.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The main outcome measure was the BDI. Others included the Brief Symptom Inventory, the Inventory of Interpersonal Problems and the Social Adjustment Scale. All tests were given at initial, 6- and 12-month assessments. Comprehensive costs were also estimated, and combined with changes in outcomes to examine between-group differences and whether counselling was more cost-effective than standard GP care.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
15/08/1995

Completion date
14/07/1999

Eligibility

Key inclusion criteria
Patients were screened at GP practices and asked to participate if they scored 14 on the Beck Depression Inventory (BDI), had suffered depression or depression/anxiety for 6 months or more, were aged 18-70 and had no history of drug or alcohol abuse, psychosis or suicidal tendencies.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
181

Total final enrolment
181

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
15/08/1995

Date of final enrolment
14/07/1999

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dept of Psychology
London
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SE9 2UG

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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 in:HTA monograph)	01/09/2000		Yes	No