

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

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Registration date 25/04/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/07/2019	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

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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

United Kingdom

SE9 2UG

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

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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