ISRCTN93023252 https://doi.org/10.1186/ISRCTN93023252

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

Contact name
Prof Roslyn Corney

Contact details
Dept of Psychology
Southwood Side
University of Greenwich
Avery Hill Road
Eltham
London
United Kingdom
SE9 2UG
+44 (0)20 8331 9160
R.H.CORNEY@greenwich.ac.uk

Additional identifiers

Protocol serial number
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.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
Not provided at time of registration.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

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
United Kingdom

England

Study participating centre
Dept of Psychology
London
United Kingdom
SE9 2UG

Sponsor information

Organisation
Department of Health (UK)

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

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