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Effectiveness of counselling, cognitive behavioural therapy and GP care for depression in general practice

Submission date
25/04/2003

Recruitment status
No longer recruiting

Registration date
25/04/2003

Overall study status
Completed

Last Edited
27/08/2009

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 Michael King

Contact details
Department of Psychiatry and Behavioural Sciences
Royal Free and University College Medical School
Royal Free Campus
Rowland Hill Street
London
United Kingdom
NW3 2PF
+44 (0)20 7830 2397
m.king@rfc.ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 93/07/66

Study information

Scientific Title

Study objectives
The aim of this study was to determine both the clinical and cost-effectiveness of usual general practitioner (GP) care compared with two types of brief psychological therapy (non-directive counselling and cognitive¿behaviour therapy) in the management of depression as well as mixed anxiety and depression in the primary care setting.

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)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Mental and behavioural disorders: Depression, anxiety, neuroses

Interventions
The design was principally a pragmatic randomised controlled trial, but was accompanied by two additional allocation methods allowing patient preference: the option of a specific choice of treatment (preference allocation) and the option to be randomised between the psychological therapies only. Of the 464 patients allocated to the three treatments, 197 were randomised between the three treatments, 137 chose a specific treatment, and 130 were randomised between the psychological therapies only. The patients underwent follow-up assessments at 4 and 12 months.
The interventions consisted of brief psychological therapy (12 sessions maximum) or usual GP care.

i. Non-directive counselling was provided by counsellors who were qualified for accreditation by the British Association for Counselling.
ii. Cognitive behaviour therapy was provided by clinical psychologists who were qualified for accreditation by the British Association for Behavioural and Cognitive Psychotherapies.
iii. Usual GP care included discussions with patients and the prescription of medication, but GPs were asked to refrain from referring patients for psychological intervention for at least 4 months.
Most therapy sessions took place on a weekly basis in the general practices. By the 12-month follow-up, GP care in some cases did include referral to mental healthcare specialists.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The clinical outcomes included depressive symptoms, general psychiatric symptoms, social function and patient satisfaction. The economic outcomes included direct and indirect costs and quality of life. Assessments were carried out at baseline during face-to-face interviews as well as at 4 and 12 months in person or by post.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/10/1995

Completion date
31/01/1999

Eligibility

Key inclusion criteria
1. GP diagnosis of depression / mixed depression and anxiety
2. 18+ years of age
3. 14+ on Beck Depression Inventory (BDI)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
197

Key exclusion criteria
1. Serious suicidal intent
2. Treated with medication or psychological therapy in past 6 months
3. Unable to complete questionnaires due to language difficulties, illiteracy or learning difficulty.

Date of first enrolment
01/10/1995

Date of final enrolment
31/01/1999

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Psychiatry and Behavioural Sciences
London
United Kingdom
NW3 2PF

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
Quarry Hill
Leeds
United Kingdom
LS2 7UE
+44 (0)1132 545 843
Sheila.Greener@doh.gsi.gov.uk

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	02/12/2000		Yes	No