

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

<b>Submission date</b> 25/04/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/04/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/08/2009	<b>Condition category</b> 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 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?
<a href="#">Results article</a>	results	02/12/2000		Yes	No