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

<b>Submission date</b> 25/04/2003	<b>Recruitment status</b> No longer recruiting	Prospectively registered
		Protocol
Registration date	Overall study status	Statistical analysis plan
25/04/2003	Completed	[X] Results
<b>Last Edited</b> 11/07/2019	Condition category  Mental and Behavioural Disorders	[] Individual participant data
11/0///019	Mentaland benavioural Disorders	

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Prof Roslyn Corney

#### Contact details

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# 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.

### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### 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