# A randomised controlled trial to compare the cost-effectiveness of tricyclic antidepressants, selective serotonin re-uptake inhibitors and lofepramine

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
25/04/2003		☐ Protocol		
Registration date 25/04/2003	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 08/11/2022	<b>Condition category</b> Mental and Behavioural Disorders	[] Individual participant data		

#### Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

**Prof Christopher Thompson** 

#### Contact details

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# Additional identifiers

EudraCT/CTIS number

IRAS number

#### ClinicalTrials.gov number

#### Secondary identifying numbers

HTA 96/61/11

# Study information

#### Scientific Title

A randomised controlled trial to compare the cost-effectiveness of tricyclic antidepressants, selective serotonin re-uptake inhibitors and lofepramine

#### Acronym

**AHEAD** 

#### Study objectives

This project will be a three-arm randomised controlled open label controlled study of the cost effectiveness of tricyclic antidepressants, SSRIs and lofepramine in the primary care setting. Outcome will be assessed over a one year period using well established clinical, quality of life, and economic measures at intervals of one or three months. The objectives are 1) to compare the cost effectiveness and cost utility of the initial choice of SSRIs and tricyclic antidepressants in general practice and 2) to compare the cost effectiveness and cost utility of the initial choice of SSRIs and lofepramine in general practice.

Please note that, as of 10 January 2008, the anticipated end date of this trial has been updated from 31 July 2002 to 31 July 2003.

## Ethics approval required

Old ethics approval format

# Ethics approval(s)

Not provided at time of registration.

# Study design

Three-arm 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**

Tricyclic antidepressants, selective serotonin re-uptake inhibitors and lofepramine

#### **Intervention Type**

Drug

#### Phase

**Not Specified** 

#### Drug/device/biological/vaccine name(s)

tricyclic antidepressants, SSRIs and lofepramine

#### Primary outcome measure

Quality of life and economic measures.

Clinical outcomes are being assessed through use of the Clinical Interview Schedule, Rviesed version; the Hospital Anxiety and Depression Scale; the Euroqol; and the SF-36 Quality of Life Scale. Use of health services is being assessed through patient-completed questionnaires, and through detailed examination of general practice medical records.

#### Secondary outcome measures

Not provided at time of registration.

#### Overall study start date

01/02/1999

#### Completion date

31/07/2003

# **Eligibility**

#### Key inclusion criteria

The sample group is of 327 patients who are prescribed antidepressant drugs by their general practitioner. The sociodemographic characteristics and other features of this group will be analysed, to evaluate whether the sample is representative of the wider population of general practice patients received antidepressant treatment.

#### Participant type(s)

Patient

#### Age group

Not Specified

#### Sex

Both

# Target number of participants

327

### Key exclusion criteria

Not provided at time of registration.

#### Date of first enrolment

01/02/1999

#### Date of final enrolment

31/07/2003

# Locations

#### Countries of recruitment

England

United Kingdom

# Study participating centre

**Academic Psychiatry** 

Southampton United Kingdom SO14 0YG

# 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

Not provided at time of registration

## 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	HTA monograph	01/05/2005		Yes	No