

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

|                                        |                                                               |                                                      |
|----------------------------------------|---------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>25/04/2003   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>25/04/2003 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>08/11/2022       | <b>Condition category</b><br>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 Christopher Thompson

### Contact details

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## Additional identifiers

### Protocol serial number

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

## Study type(s)

Treatment

## 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(s)**

Quality of life and economic measures.

Clinical outcomes are being assessed through use of the Clinical Interview Schedule, Revised 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.

**Key secondary outcome(s)**

Not provided at time of registration.

**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

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**  
**Academic Psychiatry**  
Southampton  
United Kingdom  
SO14 0YG

## 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**  
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? |
|---------------------------------|---------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | HTA monograph | 01/05/2005   |            | Yes            | No              |