

A randomised controlled trial to determine the cost-effectiveness of fluoxetine for mild to moderate depression with somatic symptoms in primary care

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| Submission date 19/05/2003 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| Registration date 19/05/2003 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 04/08/2009 | Condition category 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 01/70/05

Study information

Scientific Title

Acronym

THREAD

Study objectives

The hypothesis is that fluoxetine treatment will be more effective and cost-effective than supportive care alone among patients scoring 16-19 on the Hamilton Depression Rating Scale (HDRS) but not among those scoring 12-15.

More details can be found at: <http://www.hta.ac.uk/1356>

Protocol can be found at: <http://www.nchta.org/protocols/200100700005.pdf>

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised open-label controlled parallel group 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

Depression

Interventions

Please note that, as of 17 January 2008, the anticipated end date of this trial was updated from 30 November 2007 to 31 January 2008.

Intervention:

Supportive care from the GP.

Participating GPs will be asked to see patients in both arms for review of symptoms at follow-up appointments two, four, eight, and 12 weeks after randomisation. The GPs will be free to refer patients in both arms for counselling or cognitive-behavioural treatment if this seems appropriate in their judgement. During this 12 week period, the GPs will be asked to refrain from prescribing antidepressants to patients in the control arm, although if patients become worse and in need of antidepressants in the GPs' clinical judgement, patients may be started on drug treatment but will remain in the trial, and be included in the analysis, on an intention to treat basis.

Fluoxetine prescribed by the GP.

GPs will be asked to prescribe fluoxetine for those randomised to the active treatment arm, and will be given instructions on the initial dose (20 mg for patients aged up to 64 and 10 mg for those aged 65 and over) and subsequent titration against response if necessary. At the two week follow-up appointments the GP will determine the patient's response to treatment and address any side effects. If the patient has not responded by the four week follow-up the GP will increase the dose of fluoxetine, assuming there are no side-effects. The GPs will be instructed to change the patient to an alternative drug if they judge that fluoxetine treatment has not been successful by the eight week follow-up. If it does appear successful, the GPs will be advised to continue treatment for four months after recovery.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Fluoxetine

Primary outcome measure

The primary outcome measure at 12 and 26 weeks follow-up will be the 17 item Hamilton Depression Rating Scale.

Secondary outcome measures

Secondary outcome measures will include the Beck Depression Inventory, the Short Form 36 for generic health status, the Client Service Receipt Inventory for service use costs, and a patient satisfaction questionnaire.

Overall study start date

01/09/2003

Completion date

30/01/2008

Eligibility**Key inclusion criteria**

Patients attending general practice surgeries who are found by their GPs to be suffering from a new episode of depression and potentially in need of treatment.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

300

Key exclusion criteria

Patients are excluded if they fall outside of the HDRS scores mentioned in study summary, if they are already receiving treatment for depression, if they suffer from substance misuse which requires specific treatment, if they have any active suicidal intentions or if they are too physically unwell to participate.

Date of first enrolment

01/09/2003

Date of final enrolment

30/01/2008

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Primary Medical Care Group

Southampton

United Kingdom

SO16 5ST

Sponsor information**Organisation**

University of Southampton (UK)

Sponsor details

University Road

Southampton

England
United Kingdom
SO17 1BJ

Sponsor type
University/education

Website
<http://www.soton.ac.uk/>

ROR
<https://ror.org/01ryk1543>

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 | 01/04/2009 | | Yes | No |