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

Submission date
19/05/2003

Recruitment status
No longer recruiting

Registration date
19/05/2003

Overall study status
Completed

Last Edited
04/08/2009

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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.ncchta.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
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England
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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