ISRCTN83809224 https://doi.org/10.1186/ISRCTN83809224

Randomised trial of fluoxetine and cognitive-behavioural therapy (CBT) versus fluoxetine alone in adolescents with persistent major depression (MD).

Submission date
25/04/2003

Recruitment status
No longer recruiting

Registration date
25/04/2003

Overall study status
Completed

Last Edited
01/07/2013

Condition category
Mental and Behavioural Disorders

[ ] 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 97/29/01

Study information

Scientific Title

Study objectives
The main objective is to test the principal hypothesis that the additional costs of Cognitive Behavioural Therapy (CBT) will be offset by improvements in patient outcomes and quality of life, and/or savings in the use of other health services, compared with fluoxetine alone. Other objectives are to determine whether the treatments differ (a) at follow-up, (b) in respect of other outcomes such as comorbid mental health problems and child/parent satisfaction, (c) within subgroups defined by severity.

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Mental and behavioural disorders: Depression, anxiety, neuroses

Interventions
Please note that, as of 17 January 2008, the end date of this trial was updated from 31 October 2003 to 31 May 2005.

Interventions:
Because 1/4 cases of early onset depression remit rapidly, all cases will complete a brief initial

educational/supportive intervention, and only those who still have major depression (MD) after 2 weeks will be randomised to CBT and fluoxetine or fluoxetine (stratified by severity). The design and execution of the trial, including telephone randomisation, will be supervised by the Health Care Trials Unit in Manchester (MCR) and the results will be reported in line with the CONSORT guidance.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Cost and outcome measurement: Costs of the treatments to NHS and non-NHS services will be assessed with measures developed collaboratively by the Department of Health Economics in York and by Harrington's team in MCR in two clinical trials, one of which involved adolescents who had deliberately poisoned themselves (of whom >60% had MD). Clinical effectiveness and consumer views will be assessed using a range of standardised measures at 6 weeks, at 12 weeks, and at 6 months follow-up. The primary outcome will be a clinical measure of global functioning, the Health of the Nation Outcome Scale for Children and Adolescents (HoNOSCA).

Secondary outcome measures
Other measures will include remission from depression, comorbid problems and adverse effects. Vigorous efforts will be made to ensure that outcomes are assessed without knowledge of treatment group.

Overall study start date
01/09/2000

Completion date
31/05/2005

Eligibility

Key inclusion criteria
Adolescents aged 11 through 17 years with mental disorders

Participant type(s)
Patient

Age group
Child

Lower age limit
11 Years

Upper age limit

17 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/2000

Date of final enrolment
31/05/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Child and Adolescent Psychiatry
Cambridge
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Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
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+44 (0)1132 545 843
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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

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	21/07/2007		Yes	No
Results article	results	29/01/2008		Yes	No
Results article	results	01/05/2008		Yes	No
Results article	results	01/01/2013		Yes	No