

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	☐ Prospectively registered
Registration date 25/04/2003	Overall study status Completed	☐ Protocol
Last Edited 01/07/2013	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Ian Goodyer

Contact details

Department of Child and Adolescent Psychiatry
University of Cambridge
Douglas House
18b Trumpington Road
Cambridge
United Kingdom
CB2 2AH
+44 (0)122 333 6098/99
ig104@cam.ac.uk

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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.

Completion date

31/05/2005

Eligibility

Key inclusion criteria

Adolescents aged 11 through 17 years with mental disorders

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

11 Years

Upper age limit

17 Years

Sex

All

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

United Kingdom

England

Study participating centre

Department of Child and Adolescent Psychiatry

Cambridge

United Kingdom

CB2 2AH

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

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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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