# Randomised trial of fluoxetine and cognitivebehavioural therapy (CBT) versus fluoxetine alone in adolescents with persistent major depression (MD).

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
25/04/2003		☐ Protocol		
Registration date 25/04/2003	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 01/07/2013	Condition category  Mental and Behavioural Disorders	[] 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

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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 quidance.

#### **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

#### 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 United Kingdom CB2 2AH

# Sponsor information

#### Organisation

Department of Health (UK)

# Sponsor details

Quarry House Quarry Hill Leeds United Kingdom LS2 7UE +44 (0)1132 545 843 Sheila.Greener@doh.gsi.gov.uk

# 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