ISRCTN83033550 https://doi.org/10.1186/ISRCTN83033550

Improving mood and preventing relapse with psychoanalytic psychotherapy and cognitive behaviour therapy

Submission date
14/10/2009

Recruitment status
No longer recruiting

Registration date
15/10/2009

Overall study status
Completed

Last Edited
10/06/2025

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Depression in adolescents is a very serious problem with over half of those diagnosed retaining their problem into young adulthood. The current best treatment involves psychological treatment together with an anti-depressant (fluoxetine). After 6 months only 20% show full recovery, 30% improve but are not fully recovered, a further 30% are left with a high number of residual depressive symptoms, and 20% do not respond at all. The reasons for the poor responses are unclear. Thus many patients remain at considerable risk of relapse in the weeks and months following the end of treatment. Given that depression in adulthood is one of the three most important health burdens on UK society, and adolescent brain functioning may influence later development, finding ways to decrease the risk of adolescent recurrent depression through adequate treatment of early episodes would be a major public health advance. The aim of this study is to find out whether increasing the amount and quality of psychological treatments offered in one or both of two ways will increase treatment response, reduce the level of residual symptoms and decrease the proportion of patients at risk for depressive relapse.

Who can participate?
Patients aged 11 - 17 with severe unipolar major depression

What does the study involve?
Participants are randomly allocated to one of three groups. One group receives 'treatment as usual' (TAU), generally addressing the life situation of the adolescent and the family plus fluoxetine. The other two groups also receive TAU but also have either brief psychodynamic psychotherapy or cognitive behaviour therapy, the treatments with the strongest evidence and most commonly offered routinely in the NHS but often inadequately or for too short a period. We do not expect that the specialist therapies on their own would effectively treat depression but we predict that, in conjunction with TAU, one or both the therapies will generate better outcomes than TAU alone over a 12-month period.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Cambridgeshire and Peterborough NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2009 to March 2015

Who is funding the study?
1. NIHR Health Technology Assessment Programme - HTA (UK)
2. Department of Health (UK)

Who is the main contact?
Prof. Ian Goodyer
ig104@cam.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Ian Goodyer

Contact details
Cambridgeshire and Peterborough NHS Foundation Trust
Developmental Psychiatry
Douglas House
18b Trumpington Road
Cambridge
United Kingdom
CB2 8AH
+44 (0)1223 746040
ig104@cam.ac.uk

Additional identifiers

Protocol serial number
HTA 06/05/01

Study information

Scientific Title
A pragmatic superiority relapse prevention randomised controlled trial of short term psychodynamic psychotherapy (STPP), cognitive behaviour therapy (CBT) and active clinical care (ACC) in adolescents with moderate to severe depression attending routine child and adolescent mental health clinics

Acronym

IMPACT (Improving Mood with Psychoanalytic Psychotherapy and Cognitive Behaviour Therapy)

Study objectives
We have a superiority hypothesis which will test whether: i) short term psychodynamic psychotherapy (STPP) and cognitive behaviour therapy (CBT) are independently more effective than active clinical care (ACC); ii) STPP is more effective than CBT.

Cost-effectiveness: We will test the hypothesis that the additional costs of specialised treatment are justified by improvements in effectiveness, and possibly decreased use of health and social care services in the medium term.

We also want to determine whether the treatments differ a) in user satisfaction, and b) within subgroups defined by severity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 2 Research Ethics Committee, 09/10/2009, ref: 09/H0308/137

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Unipolar major depression of moderate to severe severity

Interventions
Experimental interventions:
1. Short term psychoanalytic psychotherapy (STPP) (n=180). 30 weekly sessions of treatment; total duration of follow up: 86 weeks from entry, 56 weeks from end of treatment
2. Cognitive behaviour therapy (CBT) (n=180). 20 weekly sessions of treatment; total duration of follow up: 86 weeks from entry, 66 weeks from end of treatment

Comparator:
Active clinical care (ACC) (n=180). 12 weekly sessions of treatment; total duration of follow up: 74 weeks from entry , 66 weeks from end of treatment

All 3 arms will be allowed to prescribe oral fluoxetine 20-40 mg daily.

The initial dosage will be 10 mg (as syrup) increased to 20 mg once a day, if there are no side effects. If there is no response by 6 weeks the dose will be increased to 40 mg. The medication will be monitored by the research child psychiatrist over the trial period. Compliance will be monitored by counting returned pills/syrup bottles (in NHS practice frequent blood tests would not be acceptable and assays of SSRI levels are seldom available).

Intervention Type
Mixed

Primary outcome(s)
Persistence of self-reported depressive symptoms at 52 weeks and recurrence of symptoms by 86 weeks. The instrument is the Mood and Feelings Questionnaire (MFQ) consisting of 33 items (range 0-66, higher scores more symptoms, >27 = clinical level of depression).

Key secondary outcome(s)
1. The Health of the Nation Outcome Scale for Children and Adolescents (HoNOSCA) will be completed by the interviewer (blind to treatment arm) (range 0-68, higher score = greater level of personal impairment)
2. The Children's Depression Rating Scale completed by the clinician treating the patient (range 17-113; higher scores = greater severity)
3. Psychiatric diagnosis: Children's Schedule for Affective Disorders (K-Sads); interviewer based diagnostic measure recording presence or absence of unipolar depression and other psychiatric diagnoses at each assessment point.

All secondary outcome measures will be assessed at 0, 6, 12, 36, 52 and 86 weeks.

Completion date
31/03/2015

Eligibility

Key inclusion criteria
1. Both males and females, age 11 through 17 years
2. Current moderate to severe unipolar major depression (MD) according to the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) criteria

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

1. Generalised learning problems (clinical diagnosis) or a pervasive developmental disorder that results in an inability to complete the questionnaires, or both
2. Pregnant, or currently having sexual relations without reliable contraception
3. Currently taking another medication that may interact with a selective serotonin reuptake inhibitor (SSRI) and unable to stop this medication (uncommon)

Date of first enrolment
01/10/2009

Date of final enrolment
31/03/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cambridgeshire and Peterborough NHS Foundation Trust
Cambridge
United Kingdom
CB2 8AH

Sponsor information

Organisation
Cambridgeshire and Peterborough NHS Foundation Trust (UK)

ROR
https://ror.org/040ch0e11

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Department of Health (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/07/2016		Yes	No
Results article	results	01/02/2017		Yes	No
Results article	results	01/03/2017		Yes	No
Results article	qualitative study results	23/11/2020	25/11/2020	Yes	No
Results article	Longitudinal network analysis	09/06/2025	10/06/2025	Yes	No
Protocol article	protocol	13/07/2011		Yes	No