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Family focused treatment for Adolescents with Bipolar Disorder

Submission date
30/01/2014

Recruitment status
No longer recruiting

Registration date
30/01/2014

Overall study status
Completed

Last Edited
05/08/2020

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
Bipolar Disorder (BD) is a long-term repeating mood disorder which causes mood swings with periods of relative stability in between. It is most frequently seen in young adults (20-30 years) but recent research has shown that the onset of symptoms can occur earlier. Early onset (aged under 18) BD (EOBD) often co-occurs with other mental health and developmental disorders, making diagnosis and management more difficult. Medication has long been considered the basis of treatment and there have been a number of drugs studied in the last ten years. Psychotherapy is also recommended in addition to medication and the involvement of families is important in the management of young people with EOBD. US researchers have developed the Family Focused Treatment for Adolescents (FFT-A), which has been shown to reduce the severity and delay the recurrence of episodes. We have adapted the FFT-A to try it out within the NHS. In our initial study, families report that this treatment has 'improved relationships in the family' and they feel 'better able to cope'. This study will allow us to find out the feasibility and acceptability of this programme.

Who can participate?
Patients aged 11-18 with a confirmed diagnosis of BD and currently in remission.

What does the study involve?
Patients and their families are randomly allocated to immediate treatment or delayed treatment (after 1 year). Treatment involves about 6 months of psychotherapy, which includes psychoeducation, communication enhancement and problem solving. Each family will be asked to complete questionnaires before treatment, immediately after treatment and again after 6 months. They can also participate in an interview to have their say about the treatment.

What are the possible benefits and risks of participating?
All participants will be given contact details for the research team should they have any queries or concerns throughout the study. Should a young person become severely unwell during the study, their intervention will be postponed until they are better as assessed by Dr Sharma or their clinician.

Where is the study run from?
The study is being run by Northumberland, Tyne and Wear NHS Foundation Trust (UK). Northumbria Healthcare NHS Foundation Trust and Tees, Esk and Wear Valley are also included to help with recruitment. Patients and their families who are recruited can be seen at a NHS premises of their choice.

When is the study starting and how long is it expected to run for?
The study started in January 2014 and will run for 3 years.

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Aditya Sharma
Aditya.sharma@ncl.ac.uk

Study website
http://research.ncl.ac.uk/thefabstudy/

Contact information

Type(s)
Scientific

Contact name
Dr Joanne Neely

Contact details
Complex Neurodevelopmental Disorders Service
Walkergate Park Centre
Benfield Road
Newcastle
United Kingdom
NE6 4QD
-
joanne.neely@newcastle.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14462

Study information

Scientific Title
A feasibility study of a randomised controlled trial of a Family Focused Treatment (FFT-A UK version) in the management of Early Onset Bipolar Disorder (EOBD)

Acronym
FAB

Study objectives
1. Is it feasible to deliver the FFT-A UK version to young people (under 18 years) and their families?
2. What are the likely consent, eligibility and retention rates as well as the acceptability of being randomised to a delayed treatment arm?
3. What are service users and their familys views about taking part in an RCT and completing the study assessments and outcome measures?
4. What is the variability in the outcome measures?
The results of this feasibility study will inform the development of a larger multi-centre RCT to evaluate the clinical and cost effectiveness of FFT-A UK version as an adjunct to pharmacotherapy in the management of EOBD. Our hypothesis for the definitive RCT will be that the addition of a family focused treatment will be more effective and cost-effective in the management of EOBD than Treatment As Usual (TAU).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sunderland REC, 18/12/2013, ref. 13/NE/0117

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://research.ncl.ac.uk/thefabstudy/informationsheets/

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: Bipolar affective disorder; Disease: Bipolar affective disorder

Interventions

Family focused treatment: The intervention is a 16 session (approx. 6 month) family focused treatment with a NHS therapist, comprising of psychoeducation, enhancing communication and problem solving. Families randomised to the delayed treatment arm will get treatment as usual and the intervention after one year.
Follow Up Length: 12 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Warwick Edinburgh Mental Well-being Scale (WEMWBS); Timepoint(s): 0, 6 and 12 months

Secondary outcome measures
1. Conflict Behaviour Questionnaire (CBQ) aka Interaction Behaviour Questionnaire; Timepoint (s): 0,6,and 12 months
2. EuroQuol EQ-5D and EQ-5DY; Timepoint(s): 0,6 and 12 months
3. Qualitative interviews and focus group; Timepoint(s): after intervention
4. The McMaster Family Assessment Device FAD; Timepoint(s): 0,6 and 12 months

Overall study start date
15/01/2014

Completion date
01/08/2016

Eligibility

Key inclusion criteria
1. Confirmation of diagnosis of BD using the WASH-UK-SADS (Washington University at St. Louis Kiddie Schedule for Affective Disorders and Schizophrenia), a reliable and valid interview schedule used in research to confirm diagnosis. This eligibility assessment takes about 2-3 hours to complete
2. Fluent in the English language to be able to engage in psychotherapy
3. Typically developing with ability in the average range to engage in psychotherapy
4. Age between 11-18 years (FFT-A UK version developed for this age range)
All family members living at home or involved in the care of the young person will be invited to attend the sessions.

Participant type(s)
Patient

Age group
Child

Lower age limit
11 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 66; UK Sample Size: 66

Total final enrolment
36

Key exclusion criteria
1. Not meeting criteria for a diagnosis of BD according to the WASH-UK-SADS
2. Currently in an episode of bipolar disorder (e.g., mania/hypomania/depression/mixed episode)
3. Lack of fluency in the English language that might prevent engagement in psychotherapy
3. Low intellectual functioning that might not allow young people to engage in the psychotherapy

Date of first enrolment
15/01/2014

Date of final enrolment
01/08/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Complex Neurodevelopmental Disorders Service
Newcastle
United Kingdom
NE6 4QD

Sponsor information

Organisation
Northumberland, Tyne and Wear NHS Foundation Trust (UK)

Sponsor details

St Nicholas Hospital
Gosforth
Newcastle upon Tyne
England
United Kingdom
NE3 3XT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01ajv0n48

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0212-27060

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?
Protocol article	protocol	01/12/2015		Yes	No
Results article	results	03/08/2020	05/08/2020	Yes	No
HRA research summary			28/06/2023	No	No