

# Family focused treatment for Adolescents with Bipolar Disorder

<b>Submission date</b> 30/01/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/01/2014	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 05/08/2020	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

## Contact information

### Type(s)

Scientific

### Contact name

Dr Joanne Neely

### Contact details

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## Additional identifiers

### Protocol serial number

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 families 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

### **Primary study design**

Interventional

### **Study design**

Randomised; Interventional; Design type: Treatment

### **Study type(s)**

Treatment

### **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(s)**

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

### **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

11 Years

**Upper age limit**

18 Years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

**Complex Neurodevelopmental Disorders Service**

Newcastle

United Kingdom

NE6 4QD

## Sponsor information

**Organisation**

Northumberland, Tyne and Wear NHS Foundation Trust (UK)

**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

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?
<a href="#">Results article</a>	results	03/08/2020	05/08/2020	Yes	No
<a href="#">Protocol article</a>	protocol	01/12/2015		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes