

The FAB study

(Family focused treatment for
Adolescents with Bipolar disorder)



©Kimber Britner*

**A feasibility study of a family focused
treatment (FFT-A UK version) for early
onset (under 18 years) Bipolar Disorder**

Information sheet for parents

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Wear NHS Foundation Trust

www.ntw.nhs.uk/pic Tel: 0191 223 2545

All researchers participating in this research project have completed Level 3 Safeguarding Children training. Should any safeguarding concerns arise, the appropriate authorities will be informed.

Who is organising and funding the research?

The study has been funded by the National Institute for Health Research, Research for Patient Benefit and is overseen by the Northumberland, Tyne and Wear NHS Foundation Trust.

Trial-related injury

If you suffer from injury or illness as a result of taking part in this study, Northumberland, Tyne and Wear NHS Foundation Trust has agreed that the usual NHS procedures will be available to you. You could also contact the Patient Advice and Liaison Service (PALS) for advice.

- North of Tyne Tel: 0800 032 0202
- Tees, Esk and Wear Valley Tel: 0800 052 0219

What about the results?

The study results will be published on the Bipolar UK website (www.bipolarUK.org.uk). We will send you a report, though study reports will not be available until several months after the study has ended.

If you have any questions about the research study, please contact Dr Adi Sharma, Sir James Spence Institute, Newcastle University, Royal Victoria Infirmary, Newcastle upon Tyne, NE1 4LP.
Telephone: 07880 823 451
Email: thefabstudy@ncl.ac.uk

Thank you

Are there any costs involved?

There are no costs involved. We are able to help with expenses for transportation to help you attend appointments. Furthermore, we would like to pay your child a £10 voucher (£30 in total) to thank them for the time and effort in filling in the questionnaires.



Confidentiality

In order to meet legal obligations, a member of the research team may inspect your child's medical records. The information from which will be entered onto a computer database held at Newcastle University. This information will be retained by Newcastle University and may be passed on to the authorised regulatory authorities. Furthermore, the doctor who developed the treatment, David Miklowitz will look at 4 of the videos to make sure the therapists are carrying it out correctly. The videos will be converted into code and your child will not be identified. The records will identify your child only by a unique study number and their initials.

All information will be treated in strict confidence and stored securely. You will be given a copy of the consent form and an information sheet to keep. The anonymous information from this study will be retained until the data are analysed and stored securely for 10 years in the University, then destroyed. If you agree to participate in this study, your child's GP will be informed.



Introduction

We wish to invite you to take part in a research study. Before you decide whether to do so, please read the following information carefully and discuss it with friends, relatives and your GP if you wish. Please ask if there is anything that is not clear or if you would like more information. You will be given as much time as you want to make a decision.



What is the purpose of this study?

Young people who have bipolar disorder can struggle with mood episodes which affect their lives (i.e. relationships with friends, work and/or education) and can also impact on their family. This research project is psychotherapy (also known as talking treatment) which aims to help young people with bipolar disorder and their families to function better in 3 broad areas: a psycho education part (helping you to understand bipolar disorder better), an improving communication part (helping you and members of your family to relate to each other in a more positive way) and a problem solving part. It has been very helpful to young people and their families in America and it is important for us to know if families in England find it useful.

Why have I been invited?

You have been invited because you have a child who has Bipolar Disorder and this treatment may help both your child and your family. We would like to get 30 young people with Bipolar Disorder and their families involved.

What will happen if I decide to take part?

The study involves your child and anyone in your family who would like to take part. There are 16, one hour sessions which will take place over 6 months. Your child and members of your family will attend these sessions every week for the first 2 months and then every 2 weeks for the remaining 4 months. All sessions will be video recorded. We would like you to fill in some questionnaires before you start and after completion of the 6 month psychotherapy.



We would also like you to fill in the same questionnaires after another 6 months. The questionnaires look at how your child reacts with their friends, family, school and work/play. There is also a questionnaire to find out whether this treatment is cost-effective (i.e. is it 'value-for-money' in the NHS). All these questionnaires will take about half an hour to complete.



If you would like, you may be asked to take part in a one to one interview or a group interview so that you can let us know about your experiences of being involved in the study. About half of the people who take part will be asked if they would like to do this. You do not have to do this part if you don't want to.

What do I have to do?

Firstly we will arrange for your child to meet a doctor who will interview your child to make sure that they are well enough to take part in the study. Your child and members of your family will then fill out the questionnaires. Some families will receive the treatment straight away and some will receive the treatment 12 months later. This is called randomisation and you have a 50/50 chance of being in either group. No one has any influence over this. Whilst taking part in this study your child will still see their own doctor/psychiatrist as usual.

Do I have to take part?

Only if you want to. Participation is voluntary, you may refuse to participate or withdraw from the study at any time. You do not need to tell us why you do not want to take part. If you choose to withdraw or not to participate, your decision will in no way affect your child's treatment.

Are there any risks involved?

Should your child become unwell during the treatment, we can stop until they are feeling better and then restart at a later date, with their doctor's permission.