

# The FAB study

(Family focused treatment for  
Adolescents with Bipolar disorder)



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**A study of family focused treatment for  
early onset Bipolar Disorder**

**Patient Information 11-18 years**

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will be informed. All researchers have undertaken 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](http://www.bipolaruk.org.uk)). The study reports will not be available until several months after the study has ended and we will send you a copy.

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](mailto:thefabstudy@ncl.ac.uk)

Thank you

### Are there any costs involved?

It will not cost you anything to take part. If you need help to attend appointments, we can provide transport costs. We would also like to give you a £10 voucher (3 in total-£30) to thank you for your time.



### Confidentiality

All information will be treated in strict confidence and stored securely. You will be asked to sign a consent form and you will be given a copy to keep.



All the information will be entered onto a computer at Newcastle University. This information will be kept by Newcastle University and may be passed on to monitoring experts who will check to ensure only the required information is kept and it is stored safely and securely.

The anonymous information from this study will be kept until the data are analysed and stored securely for 10 years in the University, then it will be destroyed. The videos will be converted into code and you will not be identified. The records will identify you only by a unique study number and your initials. The doctor, David Miklowitz who developed the treatment will only look at four of the videos to make sure that the therapists are carrying it out correctly.

A member of the research team may look at your medical records. If you agree to participate in this study, your GP

### Would you like to take part in a research study?

Please read the following information carefully and ask if there is anything that you do not understand or if you would like more information.



### What is the purpose of this research study?

People who have bipolar can struggle with severe mood swings, which affect their lives and can also impact on their family.

This research project aims to study a group of young people with bipolar and their families and the effects of psychotherapy/talking treatment. 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 will also find it useful.



The psychotherapy will focus on 3 broad areas:

- psycho-education (helping you to understand bipolar better);
- improving communication (helping you and members of your family to relate to each other in a more positive way);
- Problem solving.

### Why have I been invited?

You have been invited because you have a diagnosis of bipolar and this treatment may help both you and your family. We are hoping to involve 30 young people and their families in this study.

### What will happen if I decide to take part?

If you decide you would like to be part of the study, then the following things will happen:

- 16 x one hour sessions over six months. You and members of your family will attend these sessions every week for the first two months and then every two weeks for the remaining four months. All sessions will be video recorded. 30 minute questionnaires completed before and after you have finished the psychotherapy, and six months after completion.
- you may be asked to take part in a one-to-one or a group interview so that you can let us know about your experiences of being involved in the study. You do not have to do this part if you do not want to.

### What do I have to do, if I decide to take part?

If you would like to take part then:

- a doctor will interview you to make sure that you are well enough to take part in the study.
- you and members of your family will fill out the questionnaires.
- the psychotherapy will begin. 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 you will still see your own doctor/psychiatrist as usual.



### Do I have to take part?

**Only if you want to.**

It is entirely voluntary. You can refuse to participate or withdraw from the study at any time, and you do not have to tell us why. This research is separate from your medical care and support, which will not be affected.

### Are there any risks involved?

If you become unwell during the course of the psychotherapy, we can stop until you are feeling better and then start again at a later date.