

# Electronic Monitoring of Symptom Variability in Bipolar disorder



## Study Information Sheet & Consent Form

In collaboration with



[www.BipolarLab.com/eMonitoring](http://www.BipolarLab.com/eMonitoring)

**Invitation: You are invited to take part in the following study**

Title of project: **Electronic Monitoring of Symptom Variability in Bipolar disorder**

**The purpose of this study is to examine how your symptoms change from day to day using a range of electronic monitoring methodologies (mood diaries and activity monitors). Our main aim is to find out how easy and practical it will be for individuals with bipolar disorders (also known as manic depressive illness) to use such electronic systems to monitor themselves. We also want to find out how useful this type of intensive daily monitoring is for predicting the course of bipolar disorder, and any changes that occur with different treatments. The study has been granted ethics approval by the Institute of Psychiatry ethics committee (ref: 284/03), and was originally funded by the Medical Research Council. It is currently partially funded by a small grant from the British Council (Medical Informatics scheme) and the department of Psychological Medicine, and continues through the PhD project of Yanni Malliaris at the Institute of Psychiatry.**

### *What do I have to do?*

If you choose to participate you will have to go through **an initial assessment that will involve completing some brief screening questionnaires**. These will help us to determine the version of the eMonitoring that will be most suitable to your needs and our current requirements. **Then you may be invited to have an interview (lasting about 1-1.5 hours) that will help us to get to know your history a bit better**. Then, if you decide you wish to take part in the monitoring programme you will be taught how to use the electronic equipment (this brief training usually takes about 30 minutes, but may be faster or slower depending on whether you have used electronic diaries before). **Ideally, we will ask you to make a commitment to do the self-monitoring on a daily basis for about 3 months** (you may continue for as long as you think it will be useful to you but we will not be able to provide weekly support after 12 weeks). Using the electronic monitoring system to record your symptoms takes **no longer than 3-5 minutes per day**, so the actual time commitment is small.

During the 3 months that you undertake daily self-monitoring you will be in **regular telephone contact with one of our research assistants (RA)**, and you will have weekly telephone conversations about your progress (lasting about 30 minutes). Once you have finished the daily self-monitoring period you will be invited to attend a review meeting. This will last about 45 minutes and there would be four meetings over a year (one every three months) to check on the progress of your treatment and to monitor if you have experienced any major relapses. To make things easier and allow the participation of people who live outside London **we will try to do the majority of our assessments remotely** (using telephone, internet, and postal services).

### *What good does it do?*

This project will not change any of your current treatment, but with your help we will be able to understand the pros and cons of using electronic monitoring in clinics and in research, instead of relying on your memory of how you have been between appointments. Your feedback will also help us to understand how your symptoms may vary from day to day and what effect they have on your quality of life.

### *Who can take part in the project?*

We are looking for **people with a history of bipolar disorders who would be prepared to undertake regular self-monitoring using an electronic diary**. We would like to recruit **individuals who are not currently experiencing an acute episode of depression or mania, although you may have some symptoms of bipolar disorder**. It is also important that you are in contact with a community mental health team or a psychiatrist who is helping you to cope with your problems and to manage your current treatment. If you live outside the areas of the South London and Maudsley (SLAM) Trust, then we may ask to have confirmation of your diagnosis and a referral from your treating doctor. It would also be good if we had some contact with your partner, or a close friend who has regular contact with you. This is only to ensure that if something goes wrong there will be someone to contact. Our initial meeting will help you and us decide how feasible it would be for you to participate in this study, and whether it is a good time to try this. If you are suitable and wish to participate in the study, your medical records will be looked at by our research team in order to assist our assessments.

### ***What kind of electronic monitoring are you testing?***

We will use **two electronic mood diaries**. The first one is called **ChronoRecord** and runs on a personal computer (PC). The second system is called **iMonitor** and runs on a little pocket computer (Palm Personal Digital Assistant, PDA). Both systems simply require that you answer questions on a daily basis about your sleep, daily functioning, mood, symptoms, life events, and medication. Obviously, you will need to have access to a PC to use ChronoRecord, but for iMonitor we will provide you with a little pocket computer called PDA (such as a palm pilot) to use during the study. We will also give you an activity monitor (a pedometer that is a device that you wear on yourself), which simply measures your overall activity level, and is a more objective measure of your activity levels. **Due to our limited resources priority for the equipment will be given to patients who receive their services from the South London and Maudsley Trust.** For everyone else who is suitable and willing to participate we can provide the software at no cost and advise how to buy their own equipment.

The decision about whether you use our PDA diary (iMonitor) or our computer diary (ChronoRecord) (if you have access to a PC) will be made randomly. This is like the throw of a dice, and neither you nor the researcher will know which you will be asked to use until the researcher contacts a third person by telephone who will identify which system is listed next on the 'random allocation' table. However, as we are keen to know what people think of these monitoring systems and to get your views, we will also give people the opportunity to try the other method of self-monitoring if they don't like or can't use the one they are offered first.

### ***What happens to my data?***

**All the data you record and provide is confidential.** We abide to the rules of the Data Protection Act which means we have to store the data in a way that you cannot be identified personally from the information in our research files and none of the data will ever be given to anyone other than the research team. For the electronic diary you will be provided with a special password that will guarantee that only you have access to your self-monitoring records. This means that, for example, if the PDA is lost no one else will know who you are, and they will not be able to open the file with your diary in it.

### ***What do I get out of it?***

You will get the **opportunity to participate in a detailed review of the history of your problems and how you have coped with them, and then learn about methods of self-monitoring.** These may be useful in your consultations with your key worker or psychiatrist and in developing your own self-management skills. **We will provide all the training needed to use these self-monitoring systems,** and we will support you in learning to use these electronic systems throughout the study. **You will get the chance to have 12 weekly telephone discussions** where you will be able to discuss your progress and to review how things are going for you. **At the end of each month of self-monitoring we will send you the graphs showing you how you have rated the changes in your symptoms and daily functioning for you to keep.** We will cover all the costs of the equipment. This means that you get the opportunity to try these systems out and discuss their pros and cons with experts without having to buy one yourself. If you do well and manage to complete the majority of the assessments (80% of daily data & weekly chats) you will get to keep your electronic diary (the palm device & iMonitor). All suitable participants who complete successfully the initial assessment (first two interviews and questionnaires) will get the chance to win a £50 Amazon voucher or an iPod Shuffle.

### ***What if I change my mind?***

That's OK! You may withdraw at any time and no questions will be asked. **Your participation in this study is entirely voluntary, agreeing to try to do self-monitoring or agreeing and then withdrawing from the study will not affect your treatment from your usual clinical team in any way whatsoever.** We totally understand that your circumstances may change or you may find it too much trouble to do this monitoring on a daily basis – we are trying to learn how acceptable this programme is to all individuals with bipolar disorders, so even if you start the programme but then find you cannot participate anymore it will help us understand what percentage of people can continue to use these programmes and what proportion have to stop using such systems.

### ***How do I enrol for the study?***

Your consultant, keyworker or MDF facilitator/group coordinator may inform you about this study as they may think you might like to take part. They will give you contact details, but if you want to find out more about the project, you may contact **Yanni Malliaris at any time.**

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**Mr Yanni Malliaris**, Institute of Psychiatry, King's College, Departments of Psychology & Psychological Medicine, P063, De Crespigny Park Road, London, SE5 8AF, United Kingdom  
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Project Website: <http://www.BipolarLab.com/eMonitoring>  
Online Referrals: <http://refer.bipolarlab.com>

**THE MAUDSLEY BIPOLAR eMONITORING PROJECT**

**Consent form**

**Title of project:            Electronic Monitoring of Symptom Variability in Bipolar disorder**

Principal Investigator / PhD Student:  
**Yanni Malliaris**, Department of Psychology & Psychological Medicine,  
Institute of Psychiatry, King's College London  
PhD supervisors: **Dr Catherine Donaldson, Professor Chris Brewin**

I (name of participant)\_\_\_\_\_

**Give my consent to participate in the above named study.**

I also consent to:

1. Contact being made with my GP/Consultant/Treatment team/Significant other in the event of emergency (e.g. if I am unwell or I ask for help in a crisis or the researcher is very worried about me and would like my clinical team to arrange a review with me to see if I am okay)

Signature\_\_\_\_\_ Date\_\_\_\_\_

2. My patient information (medical notes) being accessed by the research team during the study

Signature\_\_\_\_\_ Date\_\_\_\_\_

3. Have all my interview sessions with the researcher digitally recorded for use only by the researcher to check what symptoms and problems I described

Signature\_\_\_\_\_ Date\_\_\_\_\_

**I have read the study information sheet, and also the nature, purpose, and procedures involved in this project have been explained to me by:**

Name\_\_\_\_\_

Signature\_\_\_\_\_ Date\_\_\_\_\_

Note to participant: If Interested in participating please send a copy of the consent form with your contact details to the postal address attached at the end of this page.

**Participants' Contact Information:**

Postal Address:

Telephone:

Email:

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Project Website: <http://www.BipolarLab.com/eMonitoring>  
Online Referrals: <http://refer.bipolarlab.com>

**Note to interviewer: Keep one signed copy for research records and give one signed copy to the respondent**