Understanding personal recovery experiences in bipolar disorder

Participant Information Sheet

We would like to invite you to take part in a research study exploring your personal recovery experiences. Before you decide whether you would like to take part, it is important that you understand why this research is being done and what it will involve. Please take the time to read the following information carefully and discuss this with others if you wish. Please ask us if there is anything that is unclear or that you would like more information about. Take time to decide whether or not you wish to take part.

What is the research project about?

There is evidence that the ways in which people with bipolar disorder think about and respond to their experiences may be associated with clinical recovery outcomes, such as severity of symptoms and course of their illness. However, recovery experience is a unique and diverse experience and rarely focuses only on symptom reduction. It is aimed to examine what other aspects of recovery are important to people with bipolar disorder and discover psychological, social and environmental factors that influence such aspects and fluctuations in recovery experiences, in both everyday life and in longer term.

Who is organising the research?

This project is being organised as a PhD research project by researchers at the Spectrum Centre for Mental Health Research at Lancaster University in collaboration with Manchester Mental Health and Social Care Trust (MMHSCT). The Chief Investigator of the project is Barbara Mezes, PhD student at Spectrum Centre. The project is being supervised by Professor Steven Jones and Dr Fiona Lobban, both of whom are qualified clinical psychologists and Co-directors of the Spectrum Centre at Lancaster University, and by Professor Damien Longson at MMHSCT, who is a consultant in Liaison Psychiatry. Recruitment is supported by local NHS Trusts. The team also includes an Advisory Panel whose members are service users and carers from across the North West. The role of the Panel will be to ensure that service user and carer views are central to the study and how it is run.

Who can take part in the study?

In order to take part you must meet all the following requirements:

• Have a primary research diagnosis of bipolar disorder, we use a diagnostic (screening) interview to check that you meet this requirement.

• Aged over 18

• Ability to understand written and spoken English

You must not have a primary diagnosis of substance or alcohol misuse, and currently be in a mood episode and/or being treated under a section of the Mental Health Act. If you have a current mood episode, you will be able to take part in the study once you are episode free for a period of four weeks and/or your section has terminated. If you are not eligible to take part in the study, you will be informed about other current studies recruiting at Spectrum Centre and will be offered the opportunity to join Spectrum Connect to be informed about future research projects at Spectrum Centre and to be connected with other service users, researchers.
and health care providers. If you are not eligible to take part in the study any data collected from you for the purpose of this study will be erased.

**Why have I been asked to take part?**

You have been asked to take part because you meet all the requirements for this study and/or because you have expressed an interest in contributing to important areas of health research such as this. Sharing your experiences with us will help to increase our understanding of what recovery experiences are like, what factors are important in affecting how you think or feel on daily basis and over longer time. We think that you could make a valuable contribution to this research project and to this expanding area of health research.

**Do I have to take part?**

You are under no obligation to take part. If you decide to take part you will be given a copy of this information sheet and asked to sign a consent form. If you decide to take part but change your mind later you are free to withdraw at any time and do not need to give us a reason. However, if you decide to withdraw after more than 14 days of participation, the information collected so far cannot be erased, and this information may still be used in the analysis and publication of this study. If you choose not to take part in the study, it will not prevent you from being informed about or taking part in research with the Spectrum Centre now or in the future. Not taking part in the study will not affect your participation in research at other organisations or your access to any other service or the standard of care you receive.

**What will taking part involve for me?**

*Screening Interviews*

If you decide to take part in the study, we will ask you to read this information sheet and the consent form carefully before completing the consent form. Once you have completed the consent form the Chief Investigator will contact you over the phone at a time convenient to you. We will complete a short interview called a SCID (Structured Clinical Interview for DSM-IV) interview with you about your mood and other experiences you may have had, just to confirm that you meet the criteria for the study. This will be carried out by a trained member of the research team and will take approximately one hour, although this may vary from person to person. We will ask you if you agree to have your interview audio-taped so that the research team can check back for any information they may miss at the time, however this is optional. Any interviews taped will be kept strictly confidential and anonymous and will not be listened to by anyone outside of the research team. If you have previously taken part in research with the Spectrum Centre, you may have taken part in an interview called a SCID interview which asks about your mood experiences. If so, we would like to access our record of your interview to use this as part of our data. If you are happy for this information to be accessed and included in this study then please consent for this on the consent form. If you have not had a SCID interview with us or do not wish for your record to be accessed, you can still take part in the study and do not need to answer to the question related to previous SCID interviews on the consent form, and you will be invited for taking part in an interview. Following this we will go through with you in detail what the study will involve. This study will look at recovery three different ways:

**Part 1**

Initially participation will involve completing some questionnaires asking about your mood, thinking style, behaviours and recovery approximately 100 people will take part in this phase. The questionnaires can be
completed online or on paper and returned via post according to your preference. There are several sets of questionnaires and it would be helpful if you could complete as many of these as possible. However, if you do not wish to do so, any you can complete will be very helpful to us. Please take as many breaks as you need when completing these questionnaires. Please note you can only complete the questionnaires once. The questionnaires will also ask you demographic questions and contact details for you and your GP or Care-coordinator for our records. We will inform your GP about your participation in any part(s) of the study. All the information that you give will be strictly confidential. We will not share any of the information that you give us with your GP or Care-coordinator, and we would only contact them if you were to tell us something which makes us concerned for your safety, in this case we will need share some information with your GP to explain why we are concerned. It is possible that in some instances we may require more information about the experiences you have had. For this reason we may ask if we can speak to your GP or another health professional who knows you. We will not access your medical records directly and we will get your permission before speaking to anyone.

Part 2

The second part of the study will investigate your day to day recovery experiences using Experience Sampling Methodology and up to 50 people will be able to take part in this phase. When you complete the consent form for the first phase we will ask whether you consent to be contacted about taking part in the ESM phase of the study. Please note that you are under no obligation to take part in the ESM phase even if you took part in the questionnaire phase and indicated that you would like to be contacted about this. Experience sampling methodology (ESM) is a way of finding out about the experiences people have over a set period of time. In order for us to do this you will be asked to keep your mobile phone with you at all times for the duration of the study. If you do not have a mobile phone or if you would prefer not to use your own phone then one can be provided to you by the research team. The study will last for one week and can be started anytime convenient to you. Each day the research team will send you a text message at 10 random times throughout each day (between 8am and 10pm). Each time you receive a text message from the research team we would like you to fill in a short set of questions in the diaries that we will give you. This will ask you about where you are, what you are doing and what you are thinking and feeling (e.g. to describe your activity since the last message and score from 1-7 how enjoyable this has been).

Before beginning this part of the study, the Chief Investigator will meet you to provide you with a mobile phone (if needed) and 7 ESM diaries (1 diary per day). During this appointment, the Chief Investigator will discuss with you exactly how the study works, how to fill in the diary and exactly what you can expect over the 7 days that you are taking part in the study. You will also be given a handbook which will have all this information written down for you. You will be able to ask any questions that you may have during this appointment, and the research team will be contactable throughout the whole study should you wish to get in touch at any point. All the information that you give will be strictly confidential. If you did not participate in the questionnaire phase of the study we will ask you to provide some relevant information for our records, this includes your and your GP’s/Care-coordinators contact details, demographic information and SCID interview (if no previous SCID record is available). If you took part in the questionnaire phase we will ask you to consent for this information to be used for the purpose of the ESM phase.
Part 3

We also would like to hear and explore unique recovery experiences, therefore we will invite up to 20 people, who participated in the questionnaire and/or the ESM phases of the study, to take part in an interview. This interview will explore factors that influence recovery in long term and in day to day, moreover important life events that have changed the ways in which you think or feel about your recovery progress. When you complete the consent form for the first phase of the study, we will ask whether you consent to be contacted about taking part in the interviews. Please note that you are under no obligation to take part in the interviews even if you took part in other phases of the study and indicated that you would like to be contacted about this. If you did not participate in previous phases of the study we will ask you to provide some relevant information for our records, this includes your and your GP’s/Care-coordinators contact details, demographic information and SCID interview (if no previous SCID record is available). If you took part in the questionnaire phase we will ask you to consent for this information to be used for the purpose of the interview phase. We will ask you to consent to have your interview audio-taped so that the Chief Investigator can make it into an anonymised written transcript for the purpose of analyses. Any interviews taped and transcribed will be kept strictly confidential and anonymous and will not be listened to or accessed by anyone outside of the research team.

Will my data be confidential?

All information (data) that is collected about you during the research will be kept strictly confidential and will be stored securely. Online data collection will be accessible via a password-protected account only to the research team. All data collected will be anonymised prior to analysis and no participants will be identifiable in the write up or publication of the results. It is important for us you are assured that all measures will be taken to guarantee the confidentiality of your participation. However, you might disclose information that is relevant to safeguarding vulnerable individuals, such as imminent risk of harm to the self or others. If such information is disclosed, a member of the research team will discuss with you that confidentiality will be broken on this occasion, and the relevant bodies or individuals (for instance, GP or Care-coordinator) will be informed.

What are the advantages and disadvantages of taking part?

We cannot and do not promise you any direct benefit from participating in this research. However, if more people take part in the study our understanding of recovery will be more accurate and the findings can support the development and use of services. You will also have the opportunity to share your experiences, talk about your thoughts and important life events that contributed to your recovery experiences, and according to our experience of conducting similar research, participants value sharing their personal experiences. All individuals taking part in this study will be making a valuable contribution to understanding the experiences of bipolar disorder and this knowledge will then be used to help design specific and appropriate treatment interventions for people with bipolar disorder.

Moreover, the ESM study will give you an opportunity to reflect on your own day to day experiences as they occur. This will be important in informing us about how daily activity patterns and the ways in which you think and respond to your experiences can influence your recovery progress. We hope that by understanding more about the experiences of people with bipolar disorder, we will be able to make valuable contributions to this area of health research.
It is not expected that you will experience any distress during or after completing this study but in the event that you do, telephone numbers for emergency contacts who can provide you with support are enclosed with this letter. It is possible that talking about personal experiences may cause distress. The researcher will be sensitive to this. Participants will have the opportunity to discuss any concerns at the end of the assessments and will be free to stop the process at any point. Following each interview the researcher will also offer the opportunity for a follow-up phone call the next day to ensure participants are feeling okay and to check whether there are any issues relating to the research which the participant wishes to discuss. We will check if there are any concerns you wish to raise and, if necessary, you will be able to talk to one of the clinical psychologists or service user researchers on the research team.

It is also possible that receiving the text messages in the ESM study may be disruptive from time to time during the study week. The research team have trialled the study themselves to make sure this does not cause too much disruption. If you do have any problems with any aspect of this research during the study week you will be able to contact our research team directly for advice and you can withdraw from the study at any point should you wish to do so.

Who has reviewed the study?

All research in the National Health Service (NHS) is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given ethical approval by NHS London Queen Square Research Ethics Committee.

What will happen to the results of the study?

If you participate in the study you will be informed of the results. The findings will form parts of a PhD project. In addition, the results will also be presented to a range of mental health professionals and service users with the aim of increasing the understanding of long term and day to day recovery experiences in bipolar disorder. It is hoped that the findings will also help to improve services and validate the experiences of other service users. The findings will be published in mental health journals and other publications with the aim of reaching a range of mental health professionals and service users.

If you would like any further information or have any questions about the study, please contact the Chief Investigator (PhD student) Barbara Mezes (Tel: 01524592622, email: b.mezes1@lancaster.ac.uk).

What do I do if something goes wrong?

It is very unlikely that you will be harmed as a result of your participation in this research. In the event that something does go wrong and you are harmed during the research and this is due to someone’s negligence then you may have grounds for a legal action for compensation against Lancaster University but you may have to pay your legal costs.

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, then in the first instance please contact the research team or the Supervisor of the study:

Professor Steven Jones, Professor of Psychology and Clinical Psychologist, Spectrum Centre for Mental Health Research, Lancaster University, Lancaster, LA1 4WY.

Telephone: 01524 593756 Email: s.jones7@lancaster.ac.uk
If you would prefer to speak to someone outside of the research team then please contact:
Professor Christine Milligan, Professor of Health & Social Geography, Division of Health Research, Lancaster University, Lancaster, LA1 4YT.
Telephone: 01524 592128   Email: ac.milligan@lancaster.ac.uk