Greater Manchester West Mental Health NHS Foundation Trust

Bipolar At Risk Trial (BART)

INFORMATION FOR PARTICIPANTS

You are being invited to take part in a research study. It is important for you to understand why the research is being done and what it will involve. Please take time to read the information carefully, and discuss it with others if you wish. Feel free to ask us if there is anything that is not clear, or if you would like more information. You may wish to read the information sheet more than once, and please take time to decide whether or not you wish to take part.

What is the purpose of the study?

Health services are beginning to recognise that it can be helpful to provide treatment and support to people who are starting to experience psychological distress. Such treatment may help to reduce the feelings of distress being experienced, and may prevent people's distress from worsening. Recent research has shown that identifying people who experience mood swings early on can prevent these problems from becoming worse.

Cognitive therapy (CT) is a talking therapy which focuses on the way people think. This approach states that our thoughts and beliefs may be linked to our moods, behaviour, physical experiences and to the events in our lives. Cognitive therapy sees these things as being interlinked, but emphasises our thoughts and beliefs as the area to focus on. An example of a different approach would be a medical doctor's emphasis on our physical experiences as the main area of focus.

The thoughts we have about an experience, or the way we interpret it, has been shown to have a powerful effect on our emotional, behavioural and physiological responses – that is, what we feel, what we do and what our bodies do. This is a central theme for cognitive therapy and is used widely for a range of problems.

Recently criteria have been developed to identify the experiences of individuals who have mood swings. This study would like to extend previous research by using the criteria to identify people with these experiences and find out if offering them cognitive therapy is helpful.

Why have I been invited to participate?

We are inviting people to take part in the study if they are experiencing mood swings. This may mean that at times you feel high in mood, which can include feeling energetic, activated and talkative. However, at other times you may feel low in mood which may mean you feel sad, tired, lacking in energy and get less pleasure from the things that you used to enjoy.

Do I have to take part?

No. As entry to the study is entirely voluntary, it is up to you to decide whether or not to take part. You should not feel under any pressure to make a decision. If you do decide to take part, you will be asked to sign a consent form. Even after signing you are still free to withdraw at any time and without giving a reason. This will not affect any of the care you may receive now or in the future.

If you do decide to take part initially and then withdraw from the study, it would be useful for us to use the information received from you up to the point of withdrawal. We will ask for your permission to do this, and we will not use your information without your consent.

What will happen to me if I take part?
You will be invited to meet with a member of the team to discuss the study and complete a 'detailed assessment' to check that your experiences meet the criteria for our study. At this appointment, the research assistant will first go through the information in this sheet once more with you and answer any questions you may have. If you still wish to take part you will be asked to read through and sign a consent form.

The research assistant will then ask you about the particular problems you are experiencing. They will ask you about the nature of these problems and how they affect your life. You will also be asked to complete some rating scales. This interview may take around 1.5 - 2 hours. The research assistant should offer you as many breaks as you need and the assessment can be spaced over two visits if you prefer.

The research assistant will then discuss the results of the detailed assessment with their supervisor (Dr Sophie Parker). After this we will give you a definite answer about whether your experiences meet the criteria for our study. We will try and let you know within approximately one week.

As part of the research, we will arrange to see you again for two follow-up appointments. These will be planned for 6 months and 12 months after your initial appointment and will be very similar to the initial assessment. You may also be asked to take part in an intervention called Cognitive Behavioural Therapy (see below).

Will this study involve treatment?
Sometimes, because we do not know which way of treating individuals is best, we need to make comparisons. Therefore, people who take part in this trial will either be allocated to receive Cognitive Behavioural Therapy plus their usual treatment **or** treatment as usual alone. The allocation to either Cognitive Behavioural Therapy plus treatment as usual or treatment as usual alone is done at random i.e. by chance. We will compare those who receive Cognitive Behavioural Therapy from the trial to those who receive only their treatment as usual. This means that half of the people that agree to take part will be offered a psychological intervention (Cognitive Behavioural Therapy) in addition to their usual treatment.

Cognitive Behavioural Therapy is a talking therapy, designed to work with people to help them to identify the effects of their thinking patterns on their mood. A maximum of 25 therapy sessions will be available focusing on the main difficulties you are experiencing at that time. You and your therapist will agree on tasks to be completed by you between therapy sessions. These tasks may involve practising skills learned in therapy, reading over information or trying out new ways of approaching your experiences.

We would like to make audio recordings of the therapy sessions so that we can check the quality and content of the therapy. You may have copies of these recordings to listen to between sessions and in the future should you find this useful. The research assistant or therapist will seek your consent to do this before making any audio recordings. These audiotapes will be available for you to listen to if you wish, and afterwards, any such recordings will be kept confidential in a locked cabinet and destroyed at the end of the study in May 2018.

You should continue to consult with your doctor regarding any medication you are taking during the study. This project does not require that you alter any of the medication you are taking.

What are the advantages and disadvantages to taking part?
The initial assessment may help to highlight any problems you are experiencing. If appropriate the team can signpost you to other services that you may find helpful.

For 50% of people in the study we hope that being randomly allocated into the Cognitive Behavioural intervention will helpful. It is possible that they will improve mental health difficulties that you are experiencing. However, this cannot be guaranteed. The information we get from this study may help us in the future to better treat people who have problems related to concerns about mood swings.

It is also possible that talking about some of these issues during the assessments may be upsetting. You will have the opportunity to discuss any concerns you have with the researchers and you are free to withdraw from the study at any point without giving a reason. If you later decide you would like to withdraw from the research, this decision will not affect any care you may receive now or in the future.

Will taking part in the study cost me anything?
You will need to make the time to attend the assessments and any therapy sessions you are offered the Cognitive Behavioural Therapy intervention. We will aim to make these appointments as convenient as possible, for example we may see you at your GP's surgery or a local service. Also we may be able to visit you at home if necessary.

You will be reimbursed £20 at the initial assessment and also at the 6 month and 12 month follow up assessments (£60 in total).

What if something goes wrong?
Taking part in the study should involve no particular risks to you, although it is possible some of the questions you are asked may make you feel distressed. You do not have to answer any questions you do not wish to. In addition, the research assistants have been trained to help people minimise any distress arising in these circumstances.

If you have concerns or complaints about any aspect of this study, you can ask to speak to the researchers who will do their best to answer your questions. Please speak to one of the research assistants (Lydia Pearson or Emmeline Joyce), or the chief investigator (Dr Sophie Parker) at Greater Manchester West Mental Health NHS Foundation Trust, on 0161 772 4642.

If you remain unhappy and wish to complain formally, you can do this by contacting the independent advisor (Kathryn Harney – contact details listed below).

What happens if I lose the capacity to consent to continue in the study?
Losing the capacity to consent means you are unable to make an informed choice at that moment in time. If you become unwell or are otherwise unable to consent to continue in the study, you will be withdrawn from the study. The researchers will still be able to use the data they have gathered up until that point, unless you have specifically requested for the information not to be used, either at the time of withdrawal or in advance.

Who will know I am participating in the study?
All participant records are confidential and as such are stored in a lockable filing cabinet in an NHS building or on NHS computer systems. Your records will be identifiable only by a unique personal code. Other people involved in your care such as your GP will be informed of your participation in the study. We will ask for your consent to inform these people.

If you are offered Cognitive Behavioural Therapy the therapist's written notes will also form part of your NHS health record. This confidential information cannot be removed even if you choose to withdraw from the study. Like all information on your health record, this is retained for up to 30 years and may be accessed by other people involved in your care. The therapist will also write to your GP to inform them of treatment progress. We will ask for your consent to do this, unless we are concerned about any harm directed to yourself or other people. Even in these circumstances we would inform you that we are planning to write to your GP. These letter(s) will generally include information about the nature of your experiences and about the understanding that you and the therapist have developed of them. Information on the therapy you have received and your progress will also be included. These letters will form part of your NHS health record and in most circumstances you can receive copies of them if you wish.

Audio recordings will not form part of your NHS health record and will therefore only be kept for 5 years following completion of the study. Apart from the researchers, no one will have access to these recordings.

Who will have access to information collected about me during this study?
Your records from the study will be confidential just as your medical records are confidential. Only the research team and those involved in your care will have access to your NHS health record. All your data from the study will be identifiable by a personalised number only and will be kept in a securely locked filing cabinet on NHS premises.

Audio recordings will be stored on a secure password protected NHS electronic shared computer drive. Only the researchers will have access to this.

What will happen to the results of the research?
After the study is completed, we will analyse the results and submit them for publication in a scientific journal. Presentations may also be given at scientific conferences. All data will be anonymous and any identifying data will not be

published. If you wish to know the outcome of our research, we will be happy to discuss this with you.

Who is organising the research?
The Chief Investigator is Dr Sophie Parker from Greater Manchester West Mental Health NHS Foundation Trust (GMW).

Lydia Pearson (GMW) and Emmeline Joyce (GMW) will be the research assistants, who will complete assessment measures over the course of the study.

The project will be based at Greater Manchester West Mental Health NHS Foundation Trust.

Who has approved the study?
Greater Manchester East Research Ethics Committee, established by the Health Research Authority.

What if I want to seek independent advice about the research study?
If you would like to seek independent advice about the study then please contact Kathryn Harney, Associate Director of Research and Development (Greater Manchester West Mental Health NHS Foundation Trust) on 0161 772 3954 or email on: kathryn.harney@gmw.nhs.uk

Please keep this information sheet. Thank you for considering this proposal.

If you want to discuss this study further, please contact Dr Sophie Parker, Lydia Pearson (Lydia.Pearson@gmw.nhs.uk; Work Landline: 0161 358 1863; Work Mobile: 07827 903 300), **or Emmeline Joyce** (Emmeline.Joyce@gmw.nhs.uk; Work Landline: 0161 358 0837; Work Mobile: 07584 206 815)

Greater Manchester West Mental Health NHS Foundation Trust
Psychosis Research Unit
Rico House
Bury New Road
Prestwich
M25 3BL
Telephone: 0161 772 4642