

of psychological difficulties.
The CBT used in the BART trial is based on the idea that how people think about their mood or other factors such as energy levels can lead to cycles of feeling, thinking and behaviour that can escalate, leading to mood swings and episodes continuing.

CBT helps to identify these cycles, and in turn to help people manage changes in mood, and to improve their quality of life. CBT could potentially provide many advantages such as helping people to recover more quickly from difficult experiences and live their lives in the way in which they would like.

### Compensation

In order to compensate you for your time we will offer you £20 at each assessment point (i.e. after the initial assessment, at your 4 month follow-up, 6 month follow-up and again at the 12 month follow-up point) totalling £80, plus a £5 supermarket voucher for a 9-month check in call. Compensation is not given for the CBT sessions. You can leave the study at any time. This will not affect your care.

#### How can I find out more?

If you would like more information, we are more than happy for you to contact a member of the research team.

To discuss taking part in this study, please contact:

Please note that if you decide to take part we will need to inform your care provider (e.g. your  $\mathsf{GP}$ ).

This project (NIHR316335) is funded by the Efficacy and Mechanism Evaluation (EME) Programme, an MRC and NIHR partnership. The views expressed in this publication are those of the author(s) and not necessarily those of the MRC, NIHR or the Department of Health and Social Care.

Participant Leaflet - BART II IRAS ID: 316335 - Version 2 Date 07/12/2022







Are you aged 16-25?

Do you experience periods of high and/or low mood that you find difficult to manage at times?

We are looking for people who may be at high risk of developing Bipolar Disorder (BD) to take part in a **research trial** looking at the possible **benefits of Cognitive Behavioural Therapy (CBT)** to help with difficulties associated with **high** and/or low mood.

#### What is this research about?

**BART II** is a research trial looking at whether a new kind of **CBT** is helpful for people who may be at risk of developing **Bipolar Disorder (BD)**. **CBT** aims to help people to understand and manage their changes in mood, and to improve their quality of life.

## What are the benefits of taking part in research?

Research studies like the **BART II** trial are important to help develop the best possible help for people experiencing mental health or emotional difficulties. Whether or not you receive therapy in this trial, feedback from previous studies suggests that trial participants often feel good about being part of something that could help provide better care for others in the future.

# What will happen if I choose to take part?

If you are interested in taking part, one of our research assistants will get in touch to discuss the trial in further detail with you. We will provide you with enough information to make an informed decision and answer any questions that you might have. We may also need to talk to someone who already knows you such as a GP, a care coordinator or mental health professional to make sure that the BART II trial is suitable for you.

We will make an appointment with you for an initial assessment with one of our research assistants, which will include completing some questionnaires. After completing the assessment, and if BART II is suitable for you.

You will be randomly allocated to one of two possible outcomes (in research trials these are called treatment 'arms'):

## Your usual treatment

People in this treatment 'arm' will receive their usual treatment meaning that people will remain free to access any other help that's available through the NHS or other organisations local to them.

Additionally, a BART II research assistant will meet with you 3 times (4, 6, and 12 months) during the next 12 months for a follow-up assessment appointment and a quick 9 month check-in phone call.

Participants in previous studies have often told us they find these appointments helpful as the assessments can give some idea of how they are progressing.

Although participants in this treatment 'arm' will not receive CBT with the BART II trial, all participants are equally valuable as it is only with a comparison between both treatment 'arms' of participants that we can accurately understand the potential benefits of the therapy

# Your usual treatment + CBT

ffeed the Co

People in this treatment 'arm' are offered the Cognitive Behavioural Therapy in addition to their usual treatment / help. The therapy is spread across approximately 26 sessions that last about 1 hour. This will usually take place in a location convenient to you such as your home, GP surgery or other venue.

In addition, a research assistant will meet with you 3 times over the next 12 months for follow-up points (at 4, 6, and 12 months) and a quick 9 month check-in phone call.