Participant Information

What is the purpose of the trial?

Bipolar disorder can be challenging to diagnose. When someone with bipolar disorder is low in mood, their symptoms are often identical to someone who suffers from depression. Because of this, the time to reach a correct diagnosis and treatment can take years, which means that a patient may receive inappropriate treatment and fail to respond to medication.

This trial is part of a research program conducted by Professor Bahn at the University of Cambridge to develop new ways of identifying bipolar disorder and depression. It aims to evaluate if with this new approach we can diagnose earlier and accurately and help patients access treatment earlier.

We have previously conducted a study called the 'Spot Depression Study', which yielded encouraging results. The Delta Trial aims to build on these results.

Trial results will be presented at scientific conferences and will be published in peer-reviewed journals. Any presented/published data will be completely anonymous.

With this trial, we also hope to take a big step towards turning our research into a diagnostic tool that can be used by patients.

What do I have to do?

You will be asked to answer an online questionnaire split into 6 separate question sessions, accessible via the Delta Trial app. These questions were developed by researchers, psychiatrists and individuals with bipolar disorder or depression. You can use a computer, tablet or mobile device to answer the questions, and all of your answers will be stored securely as soon as you provide them.

Some individuals will also be selected to complete **both** a home-use blood spot collection kit and a telephone-based interview with a trained interviewer.

All trial participants will also be asked to complete additional questions, 6 and 12 months after completing the trial.

- **What will the online questionnaire ask me about?**These six sessions will ask you about your past and present mood, lifestyle, personality, psychiatric history, general medical conditions and other personal details. The questionnaire assesses the criteria required to diagnose major depression, bipolar disorder, and other psychiatric conditions.
- **What is the blood spot collection kit?**The kit contains all the materials for you to be able to collect a dried blood spot sample at home and send it back to us in the post. The kit will be posted to your address and takes approximately 15 minutes in the morning to complete. We will assess protein patterns in your blood and use this information in our research along with the questionnaire answers.

- **What is involved in the telephone interview?** If you provide a dried blood spot sample, you may also be asked to complete a telephone-based interview carried out by a trained interviewer. This interview was developed for The World Health Organisation. You will need to provide a phone number and schedule your interview online.

How long will I be involved in the trial and how much time does it take?

Each of the 6 question sessions usually takes between 5 -20 minutes to complete, depending on your answers. We recommend you complete 1-2 sessions per day over a 6-day period; however, you can answer these questions at any time that suits you over a 2-week period.

If selected to receive a blood spot collection kit, it will arrive between 2 to 7 days after the completion of the 6 question sessions and takes 15 minutes to complete and re-pack for postage back to the CCNR.

Once your blood spot card has arrived at the CCNR, you will be invited to schedule your telephone interview (if selected to do so) for a time slot that suits you in the following few weeks. This interview should take 45 to 90 minutes.

Finally, you will receive an email at 6 and 12 months after you completed the questionnaire (or the blood spot kit and interview if selected) asking you to answer a few follow-up questions. These questions will ask you about your mental wellbeing, if you have seen a physician, if there have been changes in your diagnosis or if you have been diagnosed for the first time and (if relevant) what medication you are presently taking.

What are the benefits of taking part?

Your participation in the trial will not affect the medical care you receive or provide a clinical diagnosis, but it will benefit academic research into mental health.

We hope to keep the trial rewarding and engaging by providing you with a ‘Results Report’. This will not include a clinical diagnosis, but will discuss any mental health challenges that appear to be affecting you based on your answers. Your Results Report can be downloaded/ printed if you wish to share it with your GP or another medical professional.

Your participation could also benefit patients in the future. We hope to use the Delta Trial results to develop new tests that help to diagnose bipolar disorder earlier and more accurately than is presently done. These tests could be developed into bipolar detection tools for GPs, psychiatrists and patients, resulting in faster access to the correct treatment, a reduction in the rate of hospitalization due to manic episodes, accidents and suicide attempts, and an improvement in life quality.

How long will the trial be running for and how many people will participate?

The trial is expected to be open for 18 months from the first participant recruitment in April 2018, and closed in November 2019 when all the participants have been recruited and completed their sessions.

There will be a total of 4277 participants in the Delta Trial.

It is not expected that the trial will be suspended or prematurely terminated as this is a data collection trial and treatment is not being administered based on the results of the trial.

What are the possible disadvantages and risks of taking part?

This trial will not result in a diagnosis or a change in treatment and so is very low-risk. We have minimised any disadvantages/risks of taking part. However, you should be aware that your participation requires the following:

- **Time commitment:**The trial requires a time commitment. You will need to fit this into your schedule.
- **Personal questions:**There is a chance that some of the questions in the online questionnaire will make you feel uncomfortable.
- **A small pinprick:**If you receive a blood spot collection kit, you will need to make a small pinprick on your finger. This will involve minimal pain or discomfort. This is an optional part of the trial - you can choose whether or not you would like to receive a blood spot collection kit in the consent form.
- **Results Report:**In this report we will tell you if your mental health-related experiences gathered from your questionnaire answers fit the criteria for certain psychiatric conditions. You do not need to read your final report if you do not wish to receive this information.
- **Not to use the results to self-diagnose & treat:**This trial is for research purposes only and any information given to you in a report is for information only. Bear in mind that the report does not give you a diagnosis. A diagnosis can only be made through an in-person assessment by a medical professional. The information in your Results Report must not be used to self-medicate or stop existing treatments.

What if I no longer wish to participate?

You are free to withdraw your consent and stop participating at any point. If you wish to do this, email us at info@deltatrial.co.uk to let us know. We will send you some optional feedback questions to ask your opinion of the Delta Trial.

Confidentiality

- Your personal data (name, email address, contact information) will be stored securely and confidentially until the final 12 months follow-up is complete or upon withdrawal of consent. At this point, your personal information will be deleted from our records unless you provide permission to re-contact you for future studies and follow-up.
- During the trial your email address will be used for trial activity purposes only, including login, receiving next step notifications, and important trial information and reminders.
- If you are selected to receive a blood spot collection kit, you will need to provide your address. This will only be used to send a blood spot collection kit to you.
- If you are selected for the telephone interview, you will need to provide a telephone number. This will only be used for this interview.
- Your information will only be accessible to the researchers working on the trial. When the trial is complete, the data will be archived in a secure location according to the University of Cambridge policies and in accordance with ethics regulations.
- Your research data (data from your questionnaire, biomarker sample, and clinical interview) will be anonymous and identified by a code number only, which will not be linked to any identifying information or not traceable to you as a person.
- Information may also be used to support other research in the future, it will be shared anonymously using the identifying code only. However, in the unlikely event that the regulatory authority and ethics committee may request by law to see consent forms showing your name and related data, this will be kept confidential by these authorities.
- The data from the Delta Trial will be published in peer review papers and will be used in scientific conferences and talks by the University of Cambridge research team.
- The research we conduct with your dried blood spot (if you provide one) and with the data arising from your question answers may result in inventions or discoveries. All results of the trial are owned by the University of Cambridge. These could become the basis for new products or diagnostic or therapeutic agents. These inventions and discoveries may be of potential commercial value and may be patented and licensed.
- You will not receive any money or other benefits derived from any commercial or other products that may be developed from the use of your dried blood spot and/or trial data.

Will I be compensated for my participation?

Unfortunately, we are unable to provide any financial compensation for your participation in the trial.

You will receive a results report. This will not be a clinical diagnosis, but will include summaries and information of your answers and can be downloaded/ printed if you wish to share the report with your GP or another medical professional.

Who is conducting and funding this research?

This trial is being conducted and supervised by Prof Sabine Bahn at:

Cambridge Centre for Neuropsychiatric Research (CCNR)
The University of Cambridge, Department of Chemical Engineering and Biotechnology,
Cambridge University West Site, Philippa Fawcett Dr, Cambridge CB3 0AS

This trial has received approval from the University of Cambridge Human Biology Research Ethics Committee (Reference: HREC.2017.11)

The CCNR is funded by The University and The Stanley Medical Research Institute (SMRI), which is a US non-profit organisation/charity that supports the CCNR's research.

The online questionnaire has been developed through a collaboration with a company called Psyomics Ltd, which also manufactures the home-use kits for dried blood spot sample collection and is providing staffing support for the trial. All results of the trial are owned by the University of Cambridge

What should I do if I have more questions?

There is further information available at the Delta Trial website, including a 'frequently asked questions' section. If you have any questions, concerns, or need more details about this trial, please contact us at info@deltatrial.co.uk and we aim to respond to inquiries within 2-3 working days.

If you prefer, we can arrange a phone conversation with you, but you will need to email us to schedule a call.

Consent form

Thank you for reading the Participant Information. If you feel you would like to participate, please click "Yes" or "No" to confirm your agreement with each statement below.

By giving your full name, you will have signed the consent form.

An electronic copy of the signed Participant Information & consent form will be sent to you by email following registration.

☑ Yes ☐ No	I confirm that I have read and understood the Participant Information and I have had the opportunity to consider the information and to ask questions.
☑ Yes ☐ No	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
☑ Yes ☐ No	I understand that the information collected about me will be kept confidential (except where required by law) and used to support this trial and anonymously in relevant research.
☑ Yes ☐ No	I agree to take part in the trial and complete all the questionnaire sections.
☑ Yes ☐ No	I agree to being sent a blood spot kit and to having a telephone interview if selected. (select “No” if you do not wish to be selected).
☑ Yes ☐ No	I agree that my contact details can be used as part of the trial as specified in the Participant Information.

John Doe
Participant name

20/03/2018
Date (DD/MM/YYYY)