HELIOS-BD

Participant Information Sheet

Investigating light sensitivity in bipolar disorder (HELIOS-BD)

You are invited to take part in a research study.

To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

You may talk to others about the study if you wish. Take time to decide whether or not you wish to take part. Contact us if there is anything that is not clear, or if you would like more information.

If you require this information in an alternative format, such as Large Print, please let us know by contacting us using the details below.

If you have read the Participant Information Sheet and have decided you would like to take part, please get in touch with the research team:

Telephone: 07788512143
Email: HeliosBD@ed.ac.uk

What is the purpose of the study?

The changing levels of light across the day and night affect many of our bodily processes – from our energy and hunger levels to our body temperature, mood, and feelings of sleepiness. These daily cycles are called circadian rhythms.

Many people with bipolar disorder have disrupted circadian rhythms. This means that the timing of sleep and wake activities become out-of-sync with the standard 24-hour cycle. Circadian rhythms are greatly influenced by light levels and previous research suggests that people with bipolar disorder might have a heightened sensitivity to light, causing circadian rhythm disruption. This may be caused by changes in their retina, a part of the eye which processes light stimuli.

This study is designed to investigate whether people with bipolar disorder have an increased sensitivity to light. It will also look at whether the mood-stabilising drug lithium might act to reduce this light sensitivity.

We are aiming to recruit 180 people to this study:

- 60 people with bipolar disorder who are currently taking lithium
- 60 people with bipolar disorder who are not currently taking lithium
- 60 people without bipolar disorder

We will use a range of questionnaires and tests to collect data about day-to-day life, sleep schedules, mood and colour vision. We will also take images of participant's eyes to look for changes to the retina, as well as look at overnight levels of the circadian hormone melatonin from blood samples. This data will help us to understand how vision and sensitivity to light are different in people with bipolar disorder.

The study is arranged into three main parts (A, B and C) and collects this data over several study visits.

All participants attend the following 6 visits:

- **Baseline** study visit

  An appointment at the Royal Infirmary of Edinburgh, or online, to enrol participants onto the study and collect data about day-to-day life and health. This appointment lasts up to 1 hour.

- **Part A** study visit

  Two consecutive overnight stays at the Royal Infirmary of Edinburgh to measure hormone response to a night-time light experiment.

- **Part B** study visit

  Two 2-3 hour sessions at the University of Edinburgh to test colour perception and responses to visual stimuli. These could be done on separate days if preferable.

- **Part C** study visits

  Three 1-1.5 hour appointments at the Queen's Medical Research Institute at the University of Edinburgh (BioQuarter Little France campus) to take structural images and measurements of the retina, spread out over 18 months (at 0-, 9- and 18-month timepoints).

Ultimately, this research will provide a greater understanding of circadian disruption in bipolar disorder and may help to develop new treatment approaches in the future.

Why have I been invited to take part?

You have been asked to take part as you have with a diagnosis of bipolar disorder **OR** you have been asked to take part as a participant without bipolar disorder (for the study control group).

Am I eligible to take part?

To take part in the study you need to be over 18 years old and currently living in Scotland. You need to be registered with a GP in Scotland. You need to be able to read and understand English.

If you have a bipolar disorder diagnosis, you must not have had any episodes of depression, mania or hypomania within the 3 months prior to taking part in any aspect of the study. You can have any bipolar disorder diagnosis (Type 1 or Type 2). You can be on lithium medication or other medications for bipolar disorder, or on no medication at all.

If you do not have a bipolar disorder diagnosis and would like to take part as one of the control group participants, you must not have had a psychiatric illness or have taken psychiatric medications within the last 12 months. You must also not have a history of a severe mental illness in the past, such as psychosis or severe mood disorder, or a first-degree family relative (parent, sibling or child) with history of psychosis or severe mood disorder.

There are several other factors or conditions which would exclude someone from taking part in this study, including:

- Current involvement in another interventional research study
- Inability to complete the study assessments
- Diagnosis of sleep or circadian disorders
- Current shift work
- Regular use of melatonin, melatonin-suppressing medications (such as beta-blockers or ADHD medications) or melatonin-suppressing recreational drugs (such as cannabis, amphetamines, cocaine)
- Harmful use of, or dependence on, alcohol or drugs
- Blindness or significant visual impairments, existing eye disease such as glaucoma or AMD; previous surgery on the retina
- Epilepsy
- Claustrophobia
- Pregnancy

A member of the research team will discuss the eligibility criteria with you when they get in touch about your potential participation in the study.

Do I have to take part?

No, it is up to you whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and asked to sign a consent form.

You are free to withdraw at any time and without giving a reason. If you withdraw (unless you object) we will keep records relating to the treatment given to you, as this is valuable to the study.

Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights in any way.

How long do I have to decide to take part?

You have as long as you need to decide if you would like to take part in the research study. The research team require you to have had at least 3 days to read this Participant Information Sheet. After this amount of time, if you wish to participate, **please contact the study team via telephone 07788512143 or email HeliosBD@ed.ac.uk.**

If you want to ask the research team questions in order to make your decision, you can contact us using these same details.

What will happen if I take part?

A visual overview for participation in the HELIOS-BD study is provided at the end of this booklet.

What are the enrolment procedures?

A member of the research team will complete a screening questionnaire with you during the initial appointment (via an NHS-approved online face to face platform (Nearme), or telephone call if this is not possible) to answer any questions you might have and ask questions about your medical history, lifestyle and family history. If you have bipolar disorder, your diagnosis will be confirmed using a diagnostic tool. This is likely to take around an hour in total, and you will be asked for verbal consent to collect this initial information.

If you are eligible and wish to take part, we will arrange your study visit dates. Study visits take place on particular days of the week and the research team will work with you to try and ensure your participation suits your schedule. If you are not eligible or you no longer wish to take part, your screening data will not be kept.

At your baseline study visit (before any study activities) you will be asked to sign a consent form. A member of the research team will ask if you have any questions before enrolling in the study and will talk you through the items on the consent form. With your consent, we will write to your GP and psychiatrist (if applicable) to let them know that you are taking part in this research. This is mandatory for study participation.

When and where do the study visits take place?

There are six study visits in total. The scheduling of the initial 4 visits is flexible, and you do not have to complete the three parts in a particular order. For the imaging part of the study participants will be asked to attend two follow-up scans over an 18-month period.

The study visits take place between the Royal Infirmary of Edinburgh, University of Edinburgh, and online:

- Baseline study visit: Clinical Research Facility (Royal Infirmary of Edinburgh) or online
- Part A study visit: Clinical Research Facility (Royal Infirmary of Edinburgh)
- Part B study visit: Dugald Stewart Building (University of Edinburgh)
- Part C study visits (x3): Edinburgh Imaging Facility (QMRI, University of Edinburgh)

You will be reimbursed for the time you spend participating in the study, as well as your travel to and from study visits. If you need to arrange childcare, we can cover these costs too.

What happens at the study visits?
Each of the different study parts collect different types of data.

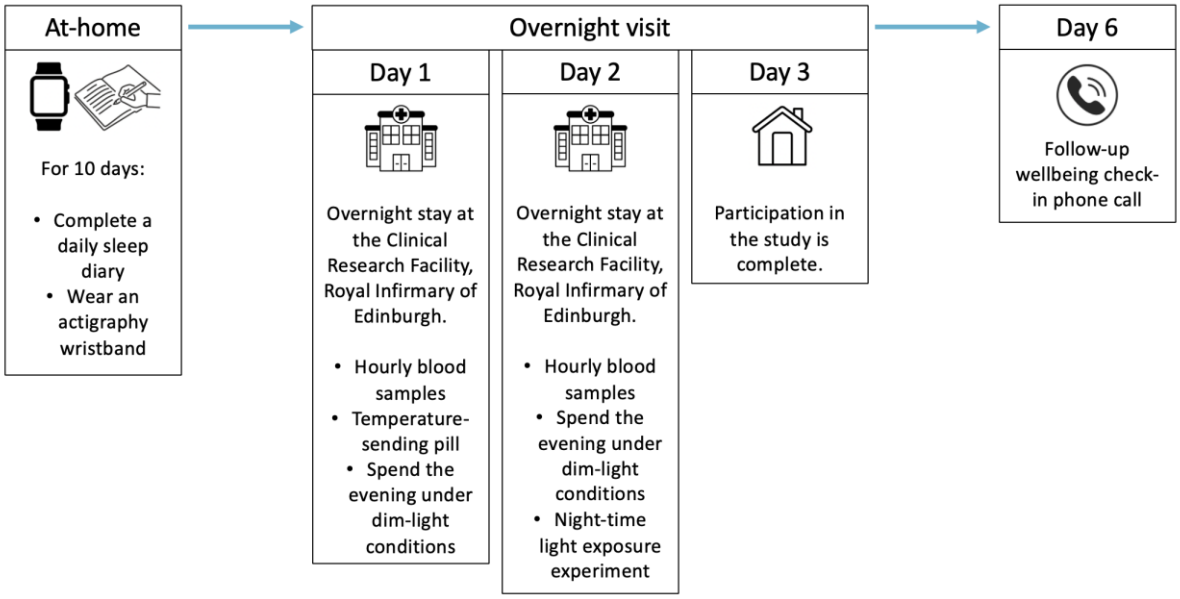
- **Baseline Study Visit**
  The baseline study visit lasts up to 1 hour. During this, we will explain each part of the study in detail and you can ask any questions you might have. If you want to take part, you will then sign the consent form and you will be officially enrolled onto the study.

  At the baseline visit, a member of the study team will ask questions about your physical and mental health and day-to-day life. You will complete several questionnaires about your sleep and daily schedules.

- **Part A**
  Part A of the study will collect data about the effects of light on circadian rhythms. Part A study visits take place at the Clinical Research Facility, Royal Infirmary of Edinburgh.

  The following image gives an overview of Part A's schedule:

PART A Overview



You will be sent a sleep diary and an actigraphy wristband to use at home for 10 days. A member of the research team will explain how to use these and written instructions will also be given. The sleep diary will collect information about your sleep and wake activity, as well as habits such as napping and caffeine and alcohol consumption. The actigraphy wristband measures your movements, but it is not a Smartwatch and does not monitor any location information. The data from this will be downloaded directly to a secure university server via a USB connection. We use the actigraphy data to look at your sleep and wake patterns.

After wearing the actigraphy wristband and completing the sleep diary for 10 days, you will attend the Clinical Research Facility at the Royal Infirmary of Edinburgh for 2 consecutive overnight stays. You will arrive to the Clinical Research Facility from 5pm on both evenings, and can leave to go home from 7am in the mornings. Meals (breakfast and dinner) and decaffeinated drinks will be provided for the duration of your overnight stays. You will not be able to eat anything during the hours of blood sampling (19:00 – 06:00), as eating can affect melatonin levels.

When you arrive on Day 1, a cannula (small plastic tube) will be inserted into an arm vein for regular blood samples to be taken. During your visit, several blood samples will be taken, including hourly blood samples and a sample for future research. Your height, weight, heart rate and blood pressure will also be measured. If you are of child-bearing potential, we will ask you to do a urinary pregnancy test to make sure you are not pregnant. This is because some parts of the Part A visits are not suitable for pregnant people.

You will then swallow a small 'temperature-sensing' pill to record your overnight core body temperature. The temperature-sensing pill is the size of a capsule tablet and measures your internal body temperature. This data is wirelessly sent to a local receiver within the clinical research facility, and then uploaded to our research computer. The pill does not record any information other than body temperature and it remains intact and will pass within 24-48 hours in your stool. Certain conditions may mean you cannot use the temperature-sensing pill, and very rarely data from the pill may be lost – in either of these cases we will use your sleep diary to estimate your body temperature changes overnight.

During your stay we ask you to wear a small device on a lanyard to measure light levels. We ask that you do not use any light-emitting devices such as mobile phones or tablets during the light-controlled hours (6pm – 6am) as this can affect your sleep and melatonin levels.

Between 5pm-10pm you will spend the evening under 'dim light' conditions. The lights will be turned off at 10pm and you will be asked to go to bed. Hourly blood samples will be taken from the cannula from 7pm until 6am by a clinical research nurse. If for any reason the cannula stops working, we may ask if we can take up to four blood samples separately. Each blood sample will be approximately 2.5ml (half a teaspoon). Every effort will be taken not to disturb you during night-time blood sampling.

On Day 2, you will be woken around 7am and provided with breakfast. The cannula will be removed from your arm. You will be free to leave the Clinical Research Facility for the day, and return from 5pm. When you return, a new cannula will be placed in your arm for blood sampling and you will again spend the evening under 'dim light' conditions, with lights-off at 10pm.

During the second night, you will be awoken in the early morning (usually between 1am-2am) and given medicated eye drops to dilate your pupils. You will then sit in front of a bright light for 30 minutes. If for any reason you do not feel well enough to sit in front of the light box, you may be asked if you feel well to try again within an hour. You will wear a headband to measure the light level. Hourly blood samples will be taken from 7pm until 6am by a clinical research nurse. However, for 90 minutes surrounding the light delivery, blood samples will be taken at 15-minute intervals. Each blood sample will be approximately 2.5ml (half a teaspoon). After the light delivery you will be able to return to bed and sleep until morning.

On Day 3, you will be woken around 7am and provided with breakfast. The cannula will be removed and you will return the actigraphy wristband and sleep diary to the research team. You will be free to leave the Clinical Research Facility and your Part A study participation will be complete.

A member of the research team will call you 3 days after the study to see how are you are and to check that the light exposure did not affect you adversely, for example, in terms of your mood.

- **Part B**

Part B of the study will collect data on how you perceive and respond to light and visual stimuli. Part B study visits take place at the Dugald Stewart Building (University of Edinburgh) in central Edinburgh.

There are two sessions in Part B – the first session measures your colour vision and pupil's responses to light, and the second session measures your brain activity in response to simple visual stimuli. Each session will last for approximately 2-3 hours.

You can either book to attend both sessions on the same day (with a longer break in between) or on separate days, as you prefer. If you book both sessions on the same day but change your mind after completing the first session, we would be happy to rebook that into a different slot.

Prior to all Part B tests, we will give you detailed instructions and an opportunity to practice and ask questions. You will also be able to take short breaks between tasks, as and when needed. If you have glasses, please bring them along and wear them. Glasses may be less tiring for performing the visual tasks than contact lenses.

In the first session, we will begin by asking you to make simple judgments about visual stimuli presented on a computer screen – for example, we will ask you to tell us if one circle on the screen is brighter than another, or if stripes on the screen are horizontal or vertical. These tests will give us very precise estimates of your sensitivities to colour and luminance contrast. We will then measure how your pupil responds to different types of light. This procedure involves the use of a device to assess your pupil's responsiveness to light in a series of tests that last about 30 minutes. It is important to try to stay as still as possible so that the pupil can be tracked effectively and we get the best measurement possible.

In the second session for Part B, we will measure the electrical activity of your brain using a commonly-used, non-invasive method called electroencephalographic (EEG). This technique involves placing a fabric waterpolo-style cap on your head, which has several of electrodes attached to it. A water-based electroconductive gel will be applied to each of the electrodes - rather than touching your scalp, the electrodes are touching the gel which is touching your skin, thus enabling them to pick up tiny electrical signals. The EEG set-up usually takes about 45 minutes. To get the best signal, it is best that you arrive with clean, dry hair with no leave-in hair products. Make sure you have a good night rest before the EEG experiment as poor sleep makes brain activity much noisier. If you had a poor sleep, feel free to contact us and reschedule.

Once the EEG is set up, you will sit in an enclosed, dimly-lit booth for about an hour (including breaks) and will watch different images presented on a large screen and complete some tasks. Your brain's electrical activity in response to these images and tasks will be recorded.

After the EEG recording, the EEG equipment will be removed, which takes 15-20 minutes. You will probably want to wash your hair after the EEG recording as the gel will leave a residue – you can either go home to do this or we have a shower facility you can use. The gel residue is easy to remove with warm water and shampoo.

- **Part C**
  Part C of the study involves imaging your eye at 3 time points: 0 months, 9 months and 18 months. Specifically, we are interested in finding out whether people with bipolar disorder have changes to their retina (the inner-most part of the eye) and if this changes over time. Part C study visits take place at the Queen's Medical Research Institute (University of Edinburgh) at the Little France campus (next to the Royal Infirmary of Edinburgh). Each Part C study visit lasts between 1 – 1.5 hours.

  Retinal imaging is non-invasive and a completely safe method of obtaining pictures of the back of the eye. Light from very low-power lasers or a camera flash enters the eye through the pupil. Light reflected back leaves the same way to be collected by the machine creating an image of the retina. These procedures are completely safe and pose no risk. You may have had similar types of imaging performed already at a high street optician for a standard eye health check-up. We now want to analyse these images in more detail to see what other information they could reveal.

  In the Imaging facility we would like to image you with a Scanning Laser Ophthalmoscope, Optical Coherence Tomography, a Fundus Camera, OCT-Angiography, Optical Biometry and Automated Perimetry, and auto refraction. These 7 methods provide different but highly informative images of the eye. The procedure for taking images is the same for each machine - you will be asked to sit in front of the machine, you will be asked to place your chin on the chin rest and look into the eyepiece. When in position, pictures of both your eyes will be taken. There is no puff of air. No eye drops are required.

  If you wear contact lenses, please come prepared to take these out for the duration of the imaging session.

<u>What happens once I have completed the study visits?</u>
Once you have completed all parts of the study, your participation will be over. You will be kept updated of the study outcomes via email or post, depending on your preference.

<u>Will I be paid for taking part?</u>
You will be reimbursed for your time at £15 per hour of study participation (estimated 38 hours in total). If you withdraw from the study, you will be paid for the time you have completed up until that point. Travel expenses (e.g. fuel, parking, taxi, public transport) and childcare costs will also be reimbursed. You will receive payment for your participation after each study appointment. If you complete all of the assessments, you will be reimbursed up to a maximum of £750, including expenses.

Receiving payment for participation may affect your tax status or any state benefits you currently receive. This is because the study payment might be treated as earnings. It is your responsibility to declare study payments to the relevant authority (for examples, HMRC or DWP). It is your choice

whether to accept the payment for participation. The National Institute for Health Research have developed some guidance on this topic, which you can read here:

https://www.nihr.ac.uk/documents/payment-guidance-for-members-of-the-public-considering-involvement-in-research/27372#section-9--more-information-on-welfare-benefits-regulations

We recommend you speak to a benefits or financial advisor regarding your personal circumstances.

What happens if new information becomes available?
Sometimes during the course of a study, new information becomes available on the condition being studied. If this happens, the study team will review the information and let you know if it affects the study. If the study changes as a result and you decide to continue in it, you will be asked to sign an updated consent form.

Is there anything I need to do or avoid?

Because this research study investigates circadian rhythms, we ask participants to follow a regular routine of sleeping in the days before attending for Part A assessments (the 48 hour stay at the Royal Infirmary of Edinburgh) and, if possible, to limit alcohol use during that time.

What are the possible benefits of taking part?

There are no direct benefits to you taking part in this study but the results from this study might help to improve the healthcare of patients in the future.

What are the possible disadvantages of taking part?

The main disadvantage of taking part in this study is the time commitment to attend study visits.
You might also experience short-term discomfort during some of the study procedures.
The following study procedures carry potential for discomfort or increased risk:

Part A

- Wearing the actigraphy wristband can cause local skin irritation.
- Cannula insertion and blood sampling can cause bruising and short-term pain.
- Ingestion of the temperature-sensing pill can cause discomfort similar to swallowing a large pill.
- The temperature-sensing pill contains electronic parts. This means that, in the rare event of a medical emergency, an MRI scan will not be possible due to presence of metal.
- Application of medicated eye drops for pupil dilation can cause sensitivity to light. Other side effects include stinging sensation, dizziness and feeling nauseous.
- Night-time light delivery and medicated eye drops may affect your ability to drive the following day. You should make sure your vision has returned to normal and you feel safe getting home before leaving the Clinical Research Facility on Day 3 of the study. If you do not feel safe getting home on Day 3, you must inform the study team and we will arrange taxi transport for you.
- Night-time light delivery may cause disruption to your sleep the following night. The timing of the light delivery will be carefully scheduled to minimise the impact on subsequent sleep.
- Night-time light delivery and sleep disruption may increase the risk of a manic or depressed mood episode for people with bipolar disorder. The timing of the light delivery will be carefully

scheduled to minimise this risk. All study participants will receive a wellbeing follow-up call after the Part A overnight stays to make sure their mood is stable, and will be encouraged to contact the study team with any concerns arising before or after this phonecall.

Part B

- Exposure to relatively bright light during pupillometry may be uncomfortable for your eyes.

Part C

- Completing several retinal images may be tiring for your eyes.

All aspects of study participation will be carefully managed to make sure you are safe at all times. If you do decide to take part in the study, please report any problems you have to the study nurse or doctor. You can also contact the study team at any time by telephone if you become worried about anything. If you develop any health problems because of your study participation, the study team will organize treatment for this.

There is a possibility that the study tests could reveal an incidental health problem that you or your doctor are unaware of. Appropriately trained members of our research team will examine your results to look for the presence of any abnormal findings, though occurrences of these are very rare. If we were to observe any such findings in our tests we would discuss this with you and inform your GP so that appropriate further tests and treatments could be arranged as necessary, for example, with an optometrist.

What if there are any problems?

If you have a concern about any aspect of this study please contact Professor Daniel Smith, Principal Investigator, at d.smith@ed.ac.uk who will do their best to answer your questions. In the unlikely event that something goes 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 NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What will happen if I don't want to carry on with the study?

You are free to withdraw from this study at any stage. If you lost capacity to consent during the study, you will be withdrawn from the study. All non-identifiable data collected up until the point of withdrawal will be retained and used, unless you specifically request for us to not use your data. Identifiable data will be retained for administration purposes until the study has concluded.

What happens when the study is finished?

When the study is finished, your personal data and research data will be stored for 15 years by the University of Edinburgh for administrative and analytic purposes, in anonymised form after 1 year.

If you are in the group taking lithium, blood sample analysis for Lithium levels will be performed by NHS Lothian services and your personal data will be used for administrative purposes. Results from Lithium level analysis will be stored on your medical records within NHS Lothian. Blood sample analysis for melatonin levels will be performed by NovoLytiX GmBH (Switzerland).

During the consent procedure we ask permission to store your data and a blood sample for future use in ethically-approved research studies. This means that anonymised data or tissue can be requested for analysis by other researchers.

Will my taking part be kept confidential?

All the information we collect will be kept confidential and there are strict laws (including the UK GDPR and Data Protection Act 2018) which safeguard your privacy at every stage.

How will we use information about you?

We will need to use information from you and your medical records for this research project.

We will collect your Community Health Index (CHI) number. Note that the CHI is a population register, used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index and is personal identifiable information. Your CHI number is being collected to allow us to review your medical records for screening and analysis purposes, but will not be transferred outside of the NHS.

Other personal identifiable information collected will include your:

- Initials
- Name
- Date of birth
- Ethnicity
- Sex
- Address & postcode
- Telephone number
- E-mail address

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number assigned instead. We will keep all information about you safe and secure within the University of Edinburgh and on secure research databases. All research data is password-protected and accessible only by the research team. University of Edinburgh policy regarding data management will be followed at all times (https://www.ed.ac.uk/information-services/about/policies-and-regulations/research-data-policy).

After the end of the study, we will make the anonymised HELIOS-BD data collected during the study available for download via the Open Science Framework (OSF, osf.io). Publishing anonymised datasets is increasingly common in science research, and means that any member of the general public is able to download and analyse the same data. This improves accessibility to research and reliability of results. You will need to consent to the publication of your anonymised data in order to participate in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but (as noted above) we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. If you agree to take part in this study, you will also have the option to allow the research team (within the sponsoring organisation) to securely store your contact details and agree to be contacted about other ethically-approved research studies. You will only be contacted by a member of this research team to determine if you are interested in taking part in another research study. Your verbal consent may then be sought to pass your contact details to another research team within the University of Edinburgh and/or NHS Lothian. Agreeing to be contacted does not oblige you to participate in further studies.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by ringing us on 07788512143 or emailing us at HeliosBD@ed.ac.uk

What will happen to the results of the study?

At the end of the study, we will provide all study participants with a results letter containing a summary of the study's findings. This study will be written up for publication in scientific journals and presented at conferences. You will not be identifiable from any published results.

Study progress updates and results will additionally be made available via the following:

1. On the HELIOD-BD website (heliosbd.com)
2. On the Bipolar Scotland website and newsletters.

Who is organising and funding the research?

This study has been organised by **the HELIOS-BD research team** and is jointly sponsored by **NHS Lothian & the University of Edinburgh.** The study is funded by The Wellcome Trust.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from **South East Scotland REC.** NHS Management Approval has also been given. The study proposal has been reviewed by The Wellcome Trust.

The HELIOS-BD Lived Experience Advisory Panel (LEAP) have informed the study design by giving feedback on the initial project proposal and by reviewing the study proposal.

How can I sign up to take part ?

If you would like to take part in the study after reading this leaflet, please contact the study team by emailing HeliosBD@ed.ac.uk or calling 07788512143 to arrange an initial screening appointment.

Researcher Contact Details

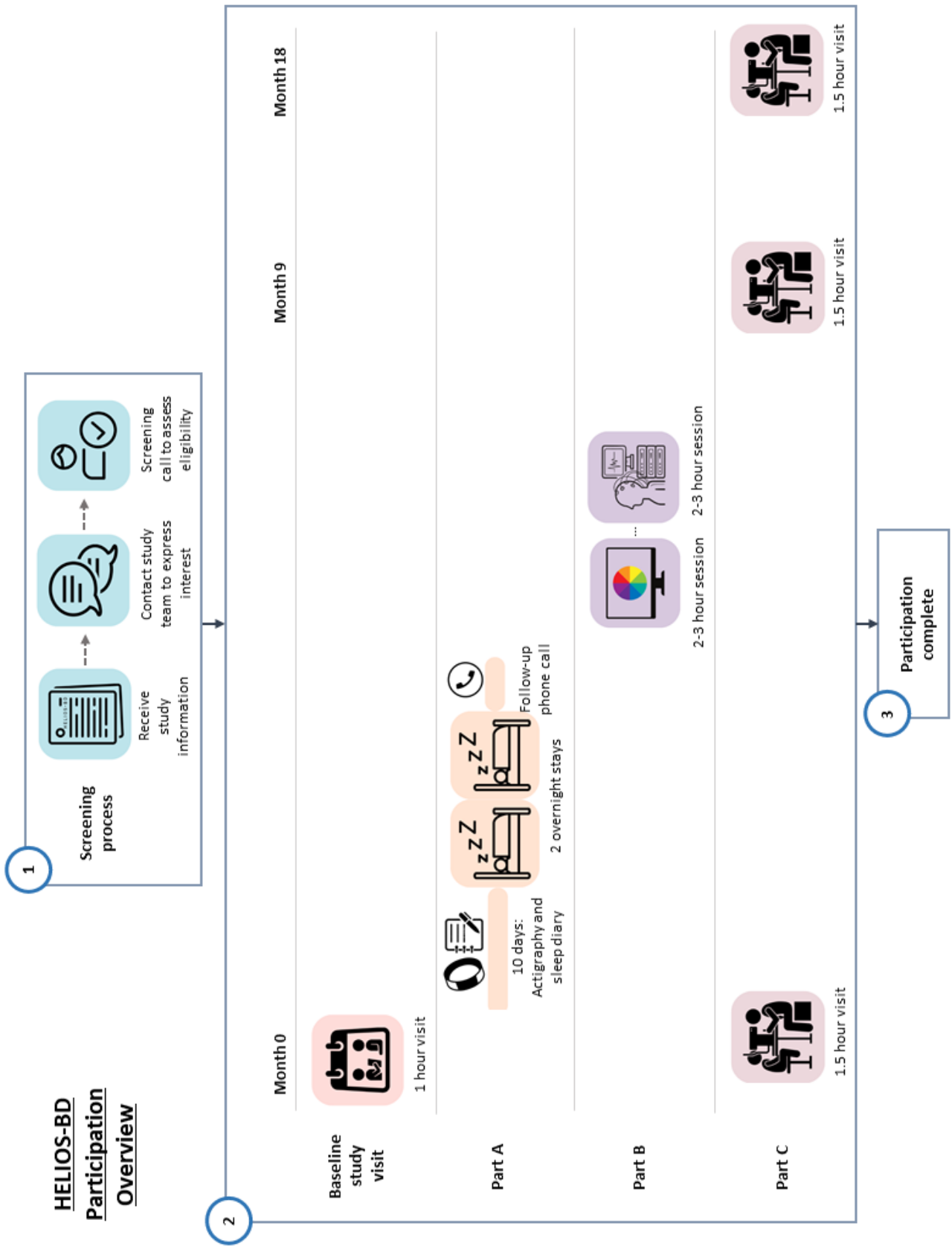
If you have any further questions about the study please contact Dr Amber Roguski or Dr Nicole Needham at HeliosBD@ed.ac.uk or by calling 07788512143.

Independent Contact Details

If you would like to discuss this study with someone independent of the study please contact Stephen Lawrie, Professor of Psychiatry and Consultant Psychiatrist at s.lawrie@ed.ac.uk.

Complaints

Please contact:
Patient Experience Team
2 – 4 Waterloo Place, Edinburgh, EH1 3EG
feedback@nhslothian.scot.nhs.uk
0131 536 3370


HELIOS-BD Participation Overview
1
Screening process
Receive study information
Contact study team to express interest
Screening call to assess eligibility
2
Month 0
Month 9
Month 18
Baseline study visit
1 hour visit
Part A
10 days: Actigraphy and sleep diary
2 overnight stays
Follow-up phone call
Part B
2-3 hour session
2-3 hour session
Part C
1.5 hour visit
1.5 hour visit
1.5 hour visit
3
Participation complete