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PARTICIPANT INFORMATION SHEET

Sleep **P**hysiology **E**ffects and **C**ircadian **T**iming: **R**outes to **U**nderstanding **M**ental Health (SPECTRUM)

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information sheet, and discuss it with others if you wish. If there is anything that is not clear or if you would like more information, please ask us.

Purpose of the study
Symptoms of depression and anxiety are common and often distressing. There are reasons to think that poor sleep is an important contributor to depression and anxiety, and if sleep could be improved, depression and anxiety might improve too.

Previous research has shown that we can improve sleep quality using behavioural interventions. While there is evidence that these behavioural treatments improve one's quality of sleep and daytime functioning, it is less clear how they affect the biology of sleep or circadian rhythms (the 'body clock'), especially in people who experience depression and /or anxiety.

In this study we want to compare two behavioural sleep interventions to understand which is more effective in changing sleep, the timing of the body clock, and mental health. Such information may help us develop new and tailored interventions for people with mental health difficulties.

It is important to note that **this study aims to examine the effects of sleep interventions on sleep and mental health but *does not provide direct clinical care***. Therefore, this study should not be seen as an alternative to any current or future treatments administered by a healthcare professional. Should you become concerned about any aspect of your physical or mental health whilst participating in this study you should consult with your doctor or other healthcare professional.

Why have I been invited?
For this study we are inviting people (aged between **18 and 30 years**) who experience depression and/or anxiety, and frequent difficulty with falling asleep and/or waking up during the night (insomnia). There are some reasons that you ***may not*** be able to take part in the study (outlined in the section below, "**What should I consider?"**). The study aims to recruit 158 participants in total.

Do I have to take part?
No, taking part in the study is entirely voluntary. If you decide to take part, you will be given this information sheet to keep and be asked to sign a consent form (this may be either online or on paper). If you decide to take part, you are free to withdraw at any time and without giving a reason. You will simply need to tell one of the research team outlined in this information sheet in person, by email, in writing, telephone or video call that you wish to withdraw. Withdrawing from the study will not affect the healthcare you receive or your legal rights. However, if you withdraw from the study, anonymised data already collected about/from you will be used in analysing the results of the study (and any personally identifiable data will be destroyed).

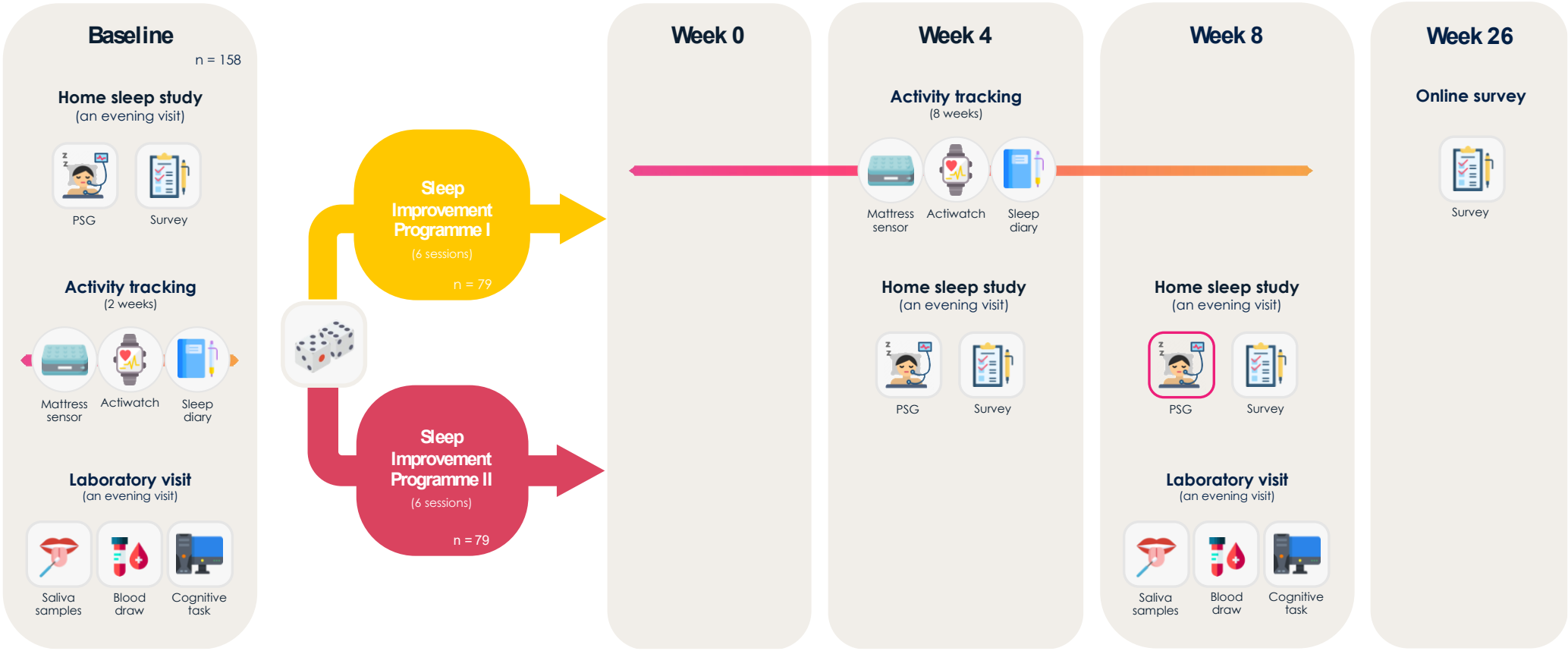
What will happen to me if I decide to take part?
If you are interested in taking part in this study, we will first ask you to complete a questionnaire (either online, over the phone or in paper format, which will take around 15 minutes) to determine whether the study is suitable for you. The questionnaire will ask about your sleep, depression and anxiety, as well as your general health. At this point you may be told you are ineligible for the study. You will be thanked for your time, and your information (which will be fully-anonymised) will not be used in the study. Any identifiable information (such as IP address) will be deleted as soon as you are found to be ineligible.

If you are eligible at this first phase, we will ask you to complete a 'Consent to be interviewed' form, and you will agree for us to collect your contact details so that we can contact you for interview either in person, by phone or by video call through Microsoft Teams. A member of the study team will then arrange an interview with you to check that you meet the eligibility criteria, and to determine if the study is suitable for you (this will take around 30 mins). In this interview, our researcher will ask you about your sleep and mental health, and about your alcohol intake and any substance use. Note that some of these questions are sensitive and of potentially upsetting topics. If you do not feel comfortable answering such questions, we would discourage you from participating in this study. Though if you do complete the interview, you will then be informed as to whether you are eligible for the study, and given a choice as to whether you would like to participate. If you are not eligible during this screening interview you will be informed on-screen, and we will retain your fully-anonymised data and your 'consent to be interviewed' form for 5 years following the completion of the trial.

If you decide to take part in this study and are considered eligible after completing the screening questionnaire and interview, you will be invited to arrange a home visit with one of our researchers

for an overnight recording of your sleep for the first of two baseline visits. This will be arranged at a date convenient for you. If you would like to get to know the researcher before the home visit, you will be able to have a brief meeting with the researcher either in our office in central Oxford, or online via video call.

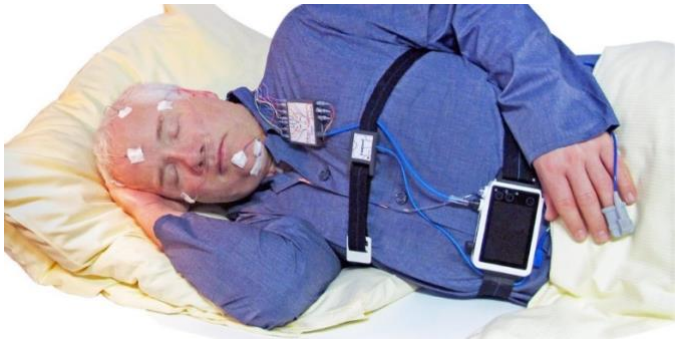
In total, there will be 6 assessment visits (one of which is online), and 6 intervention sessions (5 of which are online). The study lasts approximately 6 months in total. An overview of the visits is outlined below and shown in the figure on the next page.


Baseline
n = 158
Home sleep study
(an evening visit)
PSG
Survey
Activity tracking
(2 weeks)
Mattress sensor
Actiwatch
Sleep diary
Laboratory visit
(an evening visit)
Saliva samples
Blood draw
Cognitive task
Sleep Improvement Programme I
(6 sessions)
n = 79
Sleep Improvement Programme II
(6 sessions)
n = 79
Week 0
Week 4
Activity tracking
(8 weeks)
Mattress sensor
Actiwatch
Sleep diary
Home sleep study
(an evening visit)
PSG
Survey
Week 8
Home sleep study
(an evening visit)
PSG
Survey
Laboratory visit
(an evening visit)
Saliva samples
Blood draw
Cognitive task
Week 26
Online survey
Survey

Baseline:

Visit 1: Researchers visit to participant's home for home sleep study

- During the first evening of the home visit the researcher will arrive around 3 hours before your normal bedtime. They will initially talk to you about the study, check that you are happy to take part and give you the opportunity to ask questions. They will then complete a consent form with you.
- The researcher will ask you to complete a questionnaire (either on a laptop that the researcher will bring, your own computer/laptop or on paper) about your daytime functioning, sleep pattern and mental health. The researcher will also collect some information about you, including your age, sex, and ethnicity, and ask about any health conditions that you may have and any medications you may be using. If you prefer, you may complete the questionnaires in your own time, online, within the following 24 hours.
- The researcher will place a mattress sensor under your mattress and will show you how to initialise this using the Withing's Health Mate app. You will be required to install this on your mobile phone, create an anonymous account using details provided by the researcher, and pair the device with your home wifi. The researcher will then guide you through setting this up, according to the manufacturer's instructions. If you do not have wifi at home, the researcher will not install the mattress sensor. Once set up, you will not need to interact with the mattress sensor or the Health Mate app during the study and you will be required to logout and delete the Health Mate app. The mattress sensor measures movement and heart rate and therefore can estimate when you are asleep or awake. The mattress sensor also records audio automatically. However, this is heavily filtered to specifically identify snoring sounds only, and so speech or the content of conversations cannot be heard or interpreted. Audio recordings will not be available to us, will not be used in any analyses, are stored anonymously (with participant ID only) in the Withings cloud, and will be deleted after your data is downloaded (up to 12 months after your participation).
- The researcher will then set up the overnight sleep recording (also known as **Polysomnography, PSG**)**:** This allows us to measure exactly how long you were asleep and what time you spent in different sleep stages. Polysomnography will include an EEG (electroencephalogram) which is a common and safe form of measuring electrical activity of the brain. Small sensors (electrodes) are placed on your scalp, chin, one around each eye, and forehead for the duration of the night. To establish electrical contact between the scalp and the sensors, gel containing salts that conduct electricity are placed under each metal contact. It is often necessary to prepare the area of the scalp under the sensor by cleaning it with rubbing alcohol and massaging an abrasive substance using a cotton swab, or by scratching the surface of the scalp with a blunt wooden stick. We would ask you to let the researcher know if at any time the procedure becomes uncomfortable. In such a case, we would terminate the study procedure, without this having any negative consequences for you. The gel used to make the electrical contact is water based and washes away easily. You may find it easier to wear your pyjamas or sleeping top for this visit, to make going to bed after the device has been fitted more comfortable. The photo on the next page shows what this will look like:



- If you typically experience very sensitive skin/allergic reactions to gels and paste, then this study might not be suitable for you. Please let us know if this is the case.
- You will be provided with an actiwatch (also called actigraphy) – a wrist-worn device like a Fitbit that measures movement and light levels, allowing us to estimate your sleep-wake pattern. During the study, we kindly ask that you maintain your normal daily activities and sleep routines. The research team will guide you on how to use the actiwatch and will ask you to continuously wear it 24 hours a day, 7 days a week, throughout the whole study. You will only need to remove the watch for bathing, showering, or swimming. Note that due to the battery life, we will need to give you 4 actiwatches to use (and return) throughout the course of the study at different timepoints.
- The researcher will also ask you to complete a daily sleep diary in the morning and evening throughout the study starting on the evening of your appointment.
- The visit is expected to take approximately one and a half to two hours to complete.
- The researcher will then leave and return the following morning, around 30 minutes after your usual wake-up time to remove the electrode sensors.
- The researcher will schedule in a date for you to attend our laboratory for the next visit (if this has not already been scheduled), approximately 14 days after.

Visit 2: Laboratory visit

- After approximately 14 days you will attend the Oxford Centre for Diabetes, Endocrinology and Metabolism (OCDEM), Churchill Hospital, University of Oxford, Headington, Oxford OX3 7LE on a day convenient for you, for the second baseline visit. You will be asked to arrive around 5 and a half hours prior to your usual sleep time (i.e. at 5:30pm if your usual sleep time is 11pm), and the visit will last until 2 hours after your usual sleep time (i.e. at 1am if your usual sleep time is at 11pm). Any travel expenses will be reimbursed, and you will be booked a taxi to return home at the end of the visit.
- We ask that, 48 hours prior to your laboratory visit, you refrain from consuming caffeine, nicotine and alcohol. We additionally ask you to refrain from eating bananas, chocolate, turkey and tomatoes for the entire day before the laboratory visit. On the day of the laboratory visit, we additionally ask you to refrain from taking aspirin or any medicine that contains ibuprofen. These instructions are because specific medicines and food items are known to affect salivary melatonin, and this is what we are interested in measuring.
- The laboratory visit will take place in rooms that are of low light level, like candlelight, as we are collecting saliva samples from you that change if you are in bright light. If you need to go to a room

with more light, you will be provided with glasses to wear that will block out the light (but still make it possible to see).

- When you first arrive, a qualified research nurse will take a blood sample from you if you consent to this. This will allow us to assess the level of inflammation in your body, which has been linked to sleep disruption and mental health in previous research. Around 3.5ml (approximately 1 teaspoon) will be drawn from your non-dominant arm (unless this is unsuccessful, in which your dominant arm will be used for the blood sampling).
- Each hour you will be asked to provide a saliva sample by using a salivette (like a cotton swab), which is hygienic and easy to use. You will simply place the swab in your mouth, e.g. in your cheek, where it should remain for 2 minutes without chewing. This is to test for biomarkers (measurable signs in the body) of your biological clock.
- Each hour you will also be asked to complete a 10 minute computerised test of attention and a sleepiness scale.
- Food and drink will be provided throughout the visit. Please let the researcher know if you have any specific dietary requirements.
- You will be permitted to engage in low-level activities (e.g. listening to the radio, watching movies, working, drawing/crafts) at times when you are not required to do any tests. You may use a computer or a phone, but we will place a light filter on the screen to reduce the brightness.
- You will be asked to return the actiwatch and the completed sleep diaries, and you will be provided with new ones to wear/complete for the following 6-8 weeks during the intervention stage.

Assignment to group - treatment phase

After the baseline assessments, you will be randomly assigned by a computer to either Group 1 or Group 2. This is done at random because it is the best way to do a fair comparison of the two groups. We will randomly assign approximately 79 participants to Group 1 and approximately 79 participants to Group 2.

You will be randomly assigned to receive one of two sleep improvement programmes from a trained researcher. Both programmes will involve meeting with the researcher over 6 weekly sessions.

Sleep Improvement Programme - Group 1: participants in this group will be supported to follow a new personalised sleep schedule, which will be reviewed and adjusted each week.

Sleep Improvement Programme - Group 2: participants in this group will learn about the science of sleep and be supported with advice on how changing specific lifestyle and environmental factors can improve sleep.

Both sleep improvement programmes have the following structure:

- **Intervention Week 1** – The first session should be face-to-face with the researcher at the Sleep and Circadian Neuroscience Institute (SCNI), Dorothy Crowfoot Hodgkin Building, University of Oxford, South Parks Road, Oxford, OX1 3QU, at a day and time convenient for you (but within 2 weeks from your laboratory visit). Though if you can not attend in person,

this session can be conducted by video call (Microsoft teams). This session should take approximately 1 hour.

  - Group 1 will be provided with information on the intervention and supported to follow a new personalised sleep schedule over six weeks.
  - Group 2 will be provided with information on the intervention, including the background on the science of sleep and behavioural advice designed to improve sleep.
  - Both groups will be asked to complete a daily diary over the six weeks to help keep track of progress.

- **Intervention Weeks 2-6** – For both groups, sessions 2-6 will take place remotely. Each online meeting should last approximately 15 minutes. During this time you will continue wearing the actiwatch and filling out the sleep diaries for the remaining treatment weeks.

Your sessions with the researcher may be audio-recorded using Microsoft Teams with your consent. This is an optional part of the study and so if you decide that you do not want the sessions to be recorded, you would still continue to meet with the researcher over 6 weekly sessions.

Follow-up visits

Your participation in the study will last for 6 months and follow-up visits will take place 4 weeks and 8 weeks after the first baseline visit, and finally 6 months after your first baseline visit, irrespective of which group (1 or 2) you are allocated to.

- At 4 weeks after the first baseline visit, you will complete **Visit 3** - the **Home visit for overnight sleep study**, as outlined above, and will complete the questionnaires online.
- At 8 weeks after the first baseline visit, you will complete **Visit 4** - the **Home visit for overnight sleep study** and **Visit 5** - the **laboratory visit**, as outlined above, and will complete the questionnaires online.
- During the last morning of the home visit, the mattress sensor will be removed from your bed.
- During the second (final) laboratory visit you will return the actiwatch and sleep diaries that you have completed.
- At 6 months (26 weeks) after the first baseline visit, you will complete a questionnaire pack (**Visit 6)**. The research team will send you either an email or pack in the post asking you to complete short questionnaires online or in paper format. This is expected to take approximately 10-15 minutes.

Please note: the research team may send you reminders by email, text or phone call to complete and return the questionnaires, actiwatch and sleep diary.

If, during the course of the study, the research team becomes concerned about your health, we will inform your GP surgery so that appropriate follow-up can take place. If we pass on information to your GP surgery, we will let you know.

If you believe that you require immediate help, we advise you to contact your general practitioner, or visit your local emergency healthcare services. You may also find the following numbers useful:

- Samaritans: 116 123 (freephone). Calls to this helpline number do not appear on phone bills.
- HOPELineUK: 0800 068 4141 Calls are free from all providers and do not appear on bills. 88247 texts are free from all providers and do not appear on bills.

For information on what data we will collect about you, please see the section below in the "What will happen to my data" section.

What should I consider?
Unfortunately, you ***cannot*** take part if you:

- are pregnant or planning pregnancy in the next 6 months
- have additional sleep disorders (e.g., sleep apnoea, restless legs syndrome, or narcolepsy)
- experience alcohol or recreational drug dependency
- have epilepsy
- have a diagnosis of schizophrenia or bipolar disorder
- work night, evening, early morning, or rotating shift-work
- are currently taking certain prescribed medications for sleep (such as zopiclone, zolpidem, zaleplon)
- are currently experiencing suicidal thoughts and plan to act on these thoughts, or have recently attempted suicide
- don't have access to a computer, tablet or smartphone and an internet connection at home, or elsewhere, for treatment sessions
- cannot travel to and from Oxford City Centre or Headington
- have sensitive skin or experience allergic reactions to gels and paste

Are there any possible disadvantages and risks of taking part?
We do not anticipate that there are any risks in taking part. However, involvement in the study will mean answering questions about sensitive and potentially upsetting topics. If you do not feel comfortable answering such questions, we would discourage you from participating in the study or taking part in the online eligibility questionnaire.

Neither of the sleep improvement programmes evaluated in this study have been shown to cause any serious adverse effects. However, change to your sleep pattern during the intervention and during the laboratory visit may be associated with a short-term increase in sleepiness. Your therapist will provide support and encouragement during treatment sessions. If you do feel sleepy during the study, we advise that you avoid activities that require a high degree of vigilance, such as driving or operating heavy machinery.

Having a blood test to test for markers of inflammation is generally safe, with minor risks that include temporary pain or discomfort during the needle insertion, bruising, slight bleeding, or, rarely, a hematoma at the puncture site. Some individuals may feel lightheaded or faint, particularly if they are anxious about needles. There's a minimal risk of infection due to the skin being pierced, and allergic reactions to antiseptics or bandages are uncommon. These risks are typically minor and can be minimized with proper technique and care.

The sensors and electrodes for the PSG recordings are commonly used in sleep research and are non-invasive and only temporarily attached to the skin. EEG is a procedure for measuring brain waves. It is harmless and painless and carries no significant risk to participants. EEG recording has been used safely for many years, and we are aware of no cases of adverse events. EEG equipment comes from certified suppliers of medical equipment, who are obliged by law to adhere to published guidelines on electrical and mechanical safety (IEC-601). If you feel any discomfort, then please let the researcher know and they will stop the procedure. Slight irritation and abrasion of the skin can occur due to the cleaning and preparation of the skin. Otherwise, no further risks are expected.

If you are concerned about your mental or physical health at any time during the study, then we advise that you speak with your general practitioner.

What are the possible benefits of taking part?
We do not know what the outcome of the research will be and that is why we are conducting the research. You may benefit from improved sleep and mental health from taking part in this study. You will also contribute to research, which may help develop better treatments for people experiencing mental health problems. Furthermore, all participants who are interested in receiving a summary of the study findings will also be sent a copy of this at the end of the study.

Will my General Practitioner (GP) be informed of my participation?
If, during the study, the research team becomes concerned about your health, we will inform your GP surgery so that appropriate follow-up can take place. If we pass on information to your GP surgery we will let you know.

Will my taking part in the study be kept confidential?
Yes. All study records and samples will be identified only by a code. We will only use your name where this is necessary to contact you. Information that can identify you will only be held securely by the study team for the purposes of the study.

Confidentiality will be maintained as far as it is possible unless you tell us something which implies that you or someone you mention might be in significant danger of harm. In this case, we would have to inform the relevant authorities but we would discuss it with you first.

Confidentiality may be broken if you disclose information that indicates involvement in illegal activities that pose a significant threat to public safety (e.g., supplying drugs to minors, operating under the influence in high-risk settings). In such cases, the research team may be legally or ethically required to report this information to appropriate authorities. Any such decision will be carefully considered and, where possible, discussed with you in advance.

Responsible members of the University of Oxford, regulatory authorities and the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?
You will receive a £55 Amazon gift voucher for participating in the baseline home sleep study and the laboratory visit, a £25 Amazon gift voucher for participating in the week 4 assessments, and a final £55 Amazon gift voucher for participating in the week 8 home sleep study and the laboratory visit.

What will happen to the samples I give?
The saliva samples that you provide will be analysed for melatonin to give us an understanding of the timing of your biological clock. The blood samples that you provide will give us an understanding of inflammation in your body.

Saliva and blood samples that you provide will be stored and processed in accordance with the regulations set out in the Human Tissue Act (2004). **You will not be identifiable from this dataset. Whilst the saliva and blood samples will contain human, biological material, the samples will be destroyed immediately after analysis. All samples will be processed, analysed and destroyed up to 12 months after the end of the study.**

Saliva samples will be transferred to a laboratory in The Netherlands (Chrono@Work) for temporary storage and analysis. Identifiable data from these samples will be removed whenever possible and any data transfer will be done securely and with a similar level of data protection as required under UK law. All samples will be destroyed securely after analysis.

We would like to use data derived from your saliva samples in future studies, and to share this with other researchers (e.g. in online databases such as the Open Science Framework). **You will not be identifiable from this dataset.**

Remember, you can withdraw yourself from the research at any time, without giving a reason, and without negative consequences by advising us of this decision in person, by email, in writing, telephone or video call. However, if you withdraw from the study, unless you state otherwise, any blood or tissue samples collected to that point will be used for research as detailed in this participant information sheet. You are free to request that your blood or tissue samples are destroyed.

What will happen to my data?
Data protection legislation requires that we, the University of Oxford (whose legal name is The Chancellor Masters and Scholars of the University of Oxford), state the legal basis for processing information about you. In the case of research, this is a 'task in the public interest'. The University of Oxford is the sponsor for this study and is responsible for looking after your information and using it properly.

We will need to use information from you for this research project. We will share your information related to this research project with the following types of organisations: biomarker analysis laboratories, and data from the mattress sensor will be shared with Withings.

This information will include only your anonymous study identification number. This will be used 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 instead.

We will keep all information about you safe and secure:

- All data from sleep recordings, actiwatches, the mattress sensor, personal data from questionnaires on sleep and mental health, and treatment audio recordings will be stored and transferred securely via online systems which will be password protected on University of Oxford servers and will be deleted 5 years after the end of the study.
- Audio recordings from treatment sessions will be deleted as soon as possible after analysis (and no later than 12 months after the study ends).
- All study information collected will be made de-identified at the earliest practical opportunity.
- The information you provide at the first consultation and subsequent appointments will be coded with a study identification number so you cannot be identified from it by anyone other than the research team. The people who analyse this information will not be able to identify you or find out your contact details.
- Responsible members of the University of Oxford [and the relevant NHS Trust(s)] may be given access to data for monitoring and/or audit of the Study to ensure that the research is complying with applicable regulations.
- Data from the Mattress Sensor will be automatically uploaded to the Withings cloud server, accessed via the Withing's Health Mate app (or online equivalent), however, all data from this device will be **pseudonymised**, as the account associated with your data will only use a participant ID number. **You will not be directly identifiable from this dataset.** The storage of the data on this external cloud server complies with GDPR, and the privacy policy can be found here. As soon as your data is downloaded from the server by one of our trained team (within one week of removing the mattress sensor), the user account associated with your data on the server will be deleted. However, Withings may use anonymised sensor data for the purpose of optimizing and improving their services prior to account deletion, in line with their terms and conditions (please see here) prior to deletion.
- Paper signed consent forms will be stored in a locked filing cabinet, in a locked room within the Sleep and Circadian Neuroscience Institute (SCNi), University of Oxford for 5 years after the study has been completed. The keys to the cabinet will be kept in a code protected safe within the SCNi. The room containing the cabinet will only be accessible to a select study team, with the list of access controlled by Professor Simon Kyle within the SCNi.
- After the retention period, paper consent forms will be shredded using approved University services.
- The participant online consent to be interviewed form from eligible participants within the screening questionnaire will be exported from the online database as an excel spreadsheet. The responses will then be deleted from the online database and kept for 5 years after the study completion in the excel spreadsheet before deletion.

- Your contact details inputted into the online database (email address, name, phone number, postcode) will be exported as a password-protected Excel spreadsheet and kept for 12 months after the study ending or until public release of the research to inform participants about the results of the study. The first 3 characters of post code collected during the screening interview will be transferred from the online database to a secure server on the University's network and will be kept 12 months or until the findings of the study have been published.

International Transfers

We may share data about you outside the UK for research related purposes to:

- Analyse saliva samples for melatonin

- Allow Withings to use data from the mattress sensor to optimize and improve their services.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations: Chrono@Work and Withings.

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK.

- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website.

- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says.

- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing.

- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for the minimum period of time (3 years after the publication of the research) required by the University Policy on Management of Data, and upto 5 years after publication of the research.

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 we will keep information about you that we already have. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK by:

- asking one of the research team (Prof. Simon Kyle or Dr. Nicola Barclay)
- sending an email to **spectrum.study@ndcn.ox.ac.uk**
- calling us on **01865 618663**
- contacting the University's Data Protection Officer data.protection@admin.ox.ac.uk
- looking at the University's privacy notice available at: How we use your personal data for research purposes | Compliance

If you would like to find out more about the use of confidential data in research, the HRA has developed a general information leaflet which is available at: Patient data and research leaflet - Health Research Authority.

We may use third party service providers or subcontractors to help with some of the research activities we carry out (e.g. IT provision, survey provision, transcription services, data analytics, sample analysis etc.). We may therefore share your personal data with these providers when it is necessary to do so to allow them to carry out the services we require them to provide. However, we require all our third-party providers to have appropriate security measures in place to protect your data and we only allow them to process your data for the specific purposes we have stated in our instructions.

What will happen if I don't want to carry on with the study?
You can change your mind at any time. You will simply need to tell one of the research team outlined in this information sheet in person, by email, in writing, telephone or video call that you wish to withdraw. If you withdraw from the study, unless you state otherwise, any blood or tissue samples collected to that point will be used for research as detailed in this participant information sheet. You are free to request that your blood or tissue samples are destroyed.

What will happen to the results of this study?
The findings from the research will/may be written up as academic publications, conference presentations, research reports to funders, as summaries on research group websites, and promoted on social media. Your individual results will not be identifiable, nor would you be identified in any report or publication. After the end of the study an anonymised dataset will be created and stored for as long as it is useful, and may be shared with other researchers upon request. We will send you a copy of the study results via your preferred contact method if you tell us we can on the consent form.

What if we find something unexpected?
If, during the course of the study, the research team becomes concerned about your health, we will inform your GP surgery so that appropriate follow-up can take place. If we pass on information to your GP surgery we will let you know. However, we will not be examining any of the data for findings of clinical significance, so we will always urge you to seek medical advice if you have any concerns about your health.

What if there is a problem?
If you have a concern about any aspect of this study, please speak with Prof. Simon Kyle or Dr. Nicola Barclay (key trial contacts). They will do their best to answer your questions.

The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, 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. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, contact Prof. Simon Kyle on simon.kyle@ndcn.ox.ac.uk or 01865 617828 or you may contact University of Oxford Research Governance, Ethics & Assurance (RGEA) at rgea.complaints@admin.ox.ac.uk

How have patients and the public been involved in this study?
Patient and Public Involvement (PPI) advisors with experience of both insomnia and depression and/or anxiety have been involved in the design of the research and the reviewing of participant facing documentation.

Who is organising and funding the study?
This study is being organised by Prof. Simon Kyle and Dr. Nicola Barclay, as well as other researchers in the Sleep and Circadian Neuroscience Institute, University of Oxford. It is sponsored by the

University of Oxford, and funded by the Wellcome Trust Mental Health Award: Looking backwards, moving forwards.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by City and East Research Ethics Committee.

Further information and contact details:
If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

Study email: spectrum.study@ndcn.ox.ac.uk

SPECTRUM Study Team

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Thank you for considering taking part.