RESTED Study

Patient Information Sheet

- We would like to invite you to take part in a research study. You have been invited to take part because you may experience symptoms of Insomnia and Depression.
- Insomnia refers to frequent problems with falling asleep or staying asleep during the night. Depression refers to persistent feelings of low mood.
- This study is testing whether using a treatment to improve sleep will also improve depression and, if so, how it works.
- Before deciding if you would like to take part, we would like you to understand why the research is being done and what it would involve for you.
- Please take the time to read the information in this booklet and discuss the booklet with others if you wish. If you have any questions or if there is anything that is not clear please just ask. Our details can be found at the end of this booklet.

What is the purpose of the study?

Depression is a very common and impairing condition. There are reasons to think that poor sleep is an important contributor to depression and that if sleep could be improved, depression would improve too.

Previous research has shown that we can improve sleep quality using a nurse-supported behavioural treatment. This treatment involves reviewing your current sleep pattern and supporting you to follow a new, personalised sleep schedule.

In this study we want to find out whether using this treatment to improve sleep will improve depression and, if so, how it works.

Why have I been invited?

For this study we are inviting people (aged 18 years and over) who experience depression and frequent difficulty with falling asleep and/or waking up during the night (insomnia).

Do I have to take part?

No, taking part in the study is entirely voluntary. If you decide to take part, you will be asked to keep this information sheet and sign a consent form. If you decide not to take part, it will not affect your care from your healthcare provider.

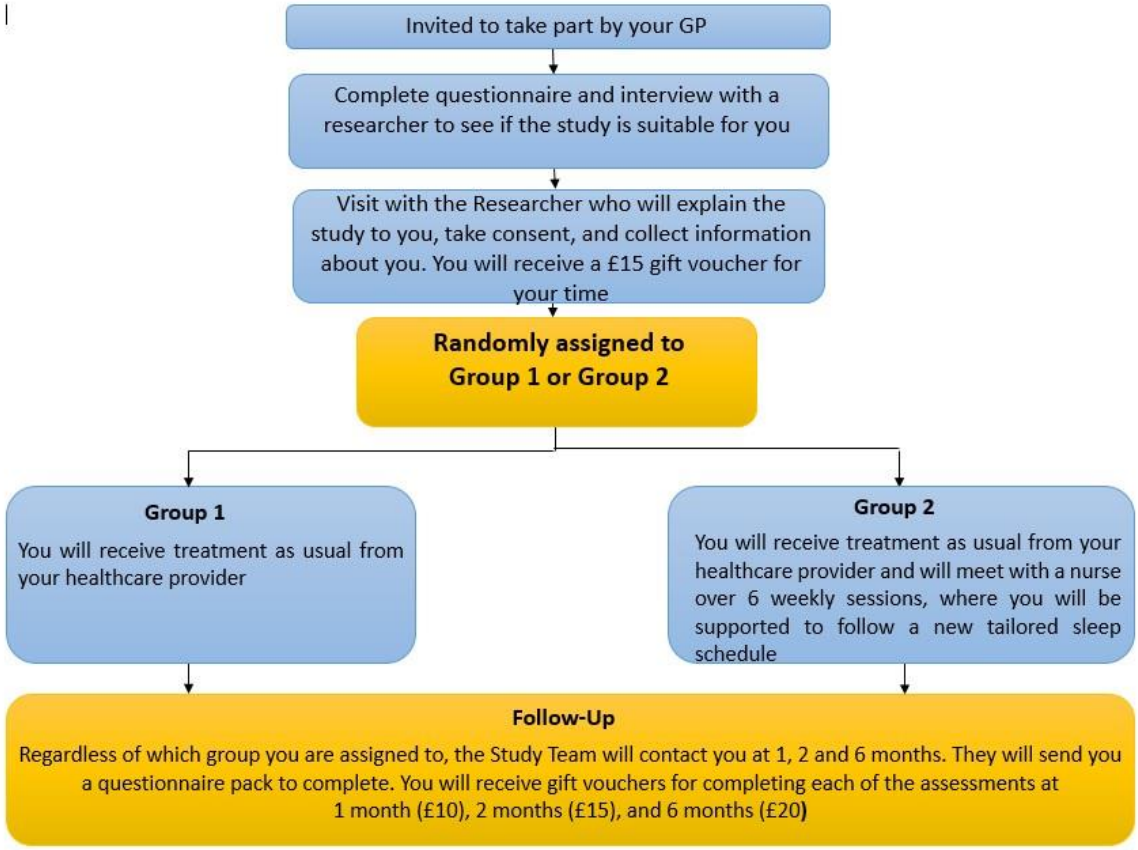
What will I have to do?

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 and your depression as well as your general health.

Please see the communication you received from your doctor to find out how you can access, complete and return the questionnaire. Alternatively, if you have not yet received communication from your doctor, you can check if you are eligible to take part in the study here: https://bit.ly/3Jq5obo

Once you have completed the questionnaire, a member of the study team will arrange a brief interview with you to check that you meet the eligibility criteria, and to determine if the study is suitable for you. We will ask you to agree for us to collect your contact details so that we can contact you for interview. In this interview, our researcher will ask you about your sleep and mental health, and also about your alcohol intake and any substance use.

If you decide to take part in this study, and are considered eligible after completing the questionnaire and interview, you will be invited to meet with one of our researchers. This meeting will either take place at your GP practice or another convenient location, or can be done via video link, such as through Microsoft Teams (or similar), if it is difficult for you to attend your GP practice.



Visit with our researcher

- The researcher will talk to you about the study. They will 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 about your health, daytime functioning, sleep pattern and mood. The researcher will also collect some information about you, including your age, gender, and ethnicity, and access your medical records to record any health conditions that you may have.
- The researcher will also ask you to complete some tasks on a computer. The tasks will ask you to judge different facial expressions and words presented on the screen.
- You will be provided with an actigraph watch, or acti-watch for short, which you will be asked to wear on your wrist for 7 days, 24 hours a day starting from the date of your appointment. An acti-watch is a wrist-worn device similar to a Fitbit that measures movement, allowing us to estimate your sleep-wake pattern.
- The researcher will also ask you to complete a daily sleep and activity diary for the next 7 days starting on the evening of your appointment.
- The researcher will give you instructions on how to use the actigraph watch and what you need to include in the sleep and activity diary at the visit.
- The visit is expected to take approximately one and a half hours to complete.

You will receive a £15 gift voucher for your time.

After the 7 days of you wearing the acti-watch and completing the sleep diary, you will be randomly assigned by a computer to either Group 1 or Group 2 (please refer to the next section “The Randomly Assigned Groups” for further details). This is done randomly because this is the best way to do a fair comparison of the two groups. We will randomise 115 patients to Group 1 and 135 patients to Group 2.

The Randomly Assigned Groups

Group 1 - will continue to receive any treatments and support from their general practitioner (or other local services). That is, there will be no additional treatment provided by the study.

Group 2 – will also continue to receive any treatments and support from their general practitioner, but in addition will also receive a behavioural sleep intervention from a nurse. This will involve meeting with the nurse over 6 weekly sessions, where you will be supported to follow a new personalised sleep schedule with the aim of improving sleep:

- **Week 1** – The first session should be face-to-face with a nurse at your GP practice. This session should take approximately 45 minutes. You will be provided with information on the intervention and supported to follow a new personalised sleep schedule over six weeks. You will be asked to complete a daily diary over the six weeks to help keep track of progress.
- **Week 2** – The second session will take place remotely. This should last approximately 15 minutes.
- **Week 3** – For the third session you will be asked to attend your GP practice again to meet with the nurse for about 30 minutes.
- **Week 4** - The fourth session will take place remotely. This should last approximately 15 minutes.
- **Week 5** - For the third session you will be asked to attend your GP practice again to meet with the nurse for about 30 minutes.
- **Week 6** – The final session will take place remotely and will last around 15 minutes.

While we have specified where meetings should take place, we will always try to be flexible. For example, if it would be too difficult for you to attend your GP practice, the sessions can be conducted through video-conferencing software (Microsoft teams) or over the phone. Your sessions with the nurse may be audio-recorded 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 nurse over 6 weekly sessions.

Follow-up assessments

Your participation in the study will last for 6 months and follow-up assessments will take place at 1, 2, and 6 months, irrespective of which group (1 or 2) you are allocated to.

The research team will send you either an email or pack in the post at 1, 2 and 6 months after your first visit to ask you to:

- Complete a questionnaire – this can be done either electronically, over the phone with one of our researchers, or in paper form. This is expected to take approximately 5-10 minutes at 1 month and 45 minutes at 2 and 6 months to complete.
- Complete computerised tasks (at 2 and 6 months only).
- Wear the acti-watch for 7 days (at 2 and 6 months only).
- Keep a sleep and activity diary for 7 days (at 2 and 6 months only).
- Send back the acti-watch and diary in a pre-paid envelope or drop off at your GP practice (at 2 and 6 months only).

Please note: the research team may send you reminders by email, text or phone call to complete and return the questionnaire, acti-watch and sleep diary. We may also speak to your GP to check that we have up to date contact details and to check whether you have been admitted to hospital during the course of the study.

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 would 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 41 41 Calls are free from all providers and do not appear on bills. 07786 209697 texts are free from all providers and do not appear on bills.

Regardless of which group (1 or 2) you are assigned to, you will receive further gift vouchers for completing each of the assessments at 1 month (£10), 2 months (£15) and 6 months (£20).

What should I consider?

The treatment offered as part of this study can be completed alongside any other treatments you may be receiving for your sleep, depression, or any other health condition. The study should not be seen as an alternative to any current or future treatments administered by a healthcare professional. 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. There are some reasons that you may not be able to take part in the study:

- if pregnant or planning pregnancy in the next 6 months, have additional sleep disorders (e.g., sleep apnoea, restless legs syndrome, or narcolepsy) or if the study team thinks that you might have one of these conditions.
- if you work night, evening, early morning, or rotating shift-work, or if you are currently receiving psychological treatment for insomnia from a health professional, or taking part in an online treatment programme for insomnia.
- if you are currently receiving cancer treatment or have a diagnosis of psychosis (schizophrenia or bipolar disorder), dementia or mild cognitive impairment, or epilepsy. You also cannot take part if you experience alcohol or recreational drug dependency.
- if you are currently experiencing suicidal thoughts and plan to act on these thoughts, or have recently attempted suicide.
- if another member of your household is already taking part in the study

Confidentiality

All data will be processed in accordance with relevant data protection legislation and all information about you will be handled in confidence. Audio recordings will be stored and transferred securely via online systems which will be password protected. 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.

The NHS will collect information from you and your medical records for this clinical study in accordance with the study's requirements. The NHS will not pass on any information not required for this study to the University of Oxford.

What will happen to my data?

UK Data protection regulation requires that we state the legal basis for processing information about you. We will be using information from you and your medical records in order to undertake this study. Research is a task that we perform in the public interest. The University of Oxford, based in the United Kingdom as sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible. We will keep identifiable information about you for 5 years after the study has finished, *with the exception of your contact details, which will kept only for up to 12 months of the study ending*. We will store the anonymised research data and any research documents with personal information, such as consent forms, securely at the University of Oxford for 5 years after the end of the study.

Your information may also be shared with third parties working with the University of Oxford for the purposes of the clinical study. We will be using a company called P1vital Products Ltd. ('P1vital') to collect, process and store some elements of data for the study (the computerised tasks). P1vital will be a data processor along with the Primary Care Clinical Trials Unit. Access to this system requires you to create a login on their data capture system, ePRO. To create this, we will require your email address. All information from these tasks is securely stored on their server and encrypted before being transferred to the research group for analysis. P1vital will use minimum personally identifiable information. P1vital will store this data until deletion is requested by us. This will take place after the study has terminated and all relevant data has been transferred to our research staff. Participants email addresses and any other personal information will be deleted from the system at the end of the study. P1vital has a contract with the University of Oxford which specifies that P1vital will not use your personal data for any reason other than this trial. P1vital reserve the right to use the anonymised computer task data and basic demographic data such as sex & age (unattached to names or identifiable information) for non-commercial, internal research purposes.

The local study team (based at your GP practice) will use your name, NHS number, home address, and contact details, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. The consent form you complete for this study will be kept for 5 years after the study has finished.

Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at: https://compliance.admin.ox.ac.uk/individual-rights. You can find out more about how we use your information by contacting the Chief Investigator (details at the end of this document).

Are there any benefits or risks to taking part?

We do not anticipate that there are any risks in taking part. However, involvement in the study will involve 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.

You may benefit from improved sleep and mood from taking part in this study. You will also contribute to research, which may help develop better treatments for people experiencing depression and poor sleep. There are no known serious side effects from taking part in this study; however, change to your sleep pattern may be associated with a short-term increase in sleepiness. 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.

What if I don't want to take part anymore?

You can leave the study at any point by contacting the trial team or your GP practice and the decision to do so will not affect the treatment you receive from your GP or nurse. Information that we have already collected for the research will still be used in the Study.

What if there are any issues?

For queries about this study, please contact the study team on the details below. If you wish to complain about any aspect of the way in which you have been treated during the study, you should contact the Chief Investigator, Dr Simon Kyle, or the Study Manager (contact details below), or the University of Oxford Research Governance, Ethics & Assurance Team (RGEA)office on 01865 616480 or email RGEA.Complaints@admin.ox.ac.uk.

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment with which you are provided.

How have patients and the public been involved in this study?

Patient and public Involvement (PPI) advisors with experience of both depression and insomnia have been involved in the design of the research and the reviewing of participant facing documentation. The following link provides general information about taking part in research.

- www.crn.nihr.ac.uk/can-help/patients-carers-public/how-to-take-part-in-a-Study/

What will happen to the results?

The results of this research study will be published on the University website, in scientific medical journals 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.

Who is organising and funding the study?

This study is being funded by the National Institute for Health Research (NIHR) Health Efficacy and Mechanism Evaluation.

The study is being conducted by the research team at the University of Oxford, and is being run across different regions within England, UK.

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 your interests. This study has been reviewed and given favourable opinion by London – Surrey Research Ethics Committee.

Contact details

If you would like to take part in this study or require any further information, you can contact the research team:

RESTED Study Team
Chief Investigator: Dr Simon Kyle
Website: **https://bit.ly/3Jq5obo**

Contact telephone number: 01865-617828